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42 CFR Parts 405, 410, 411, 414, *et al.*
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, 495

[CMS–1631–P]

RIN 0938–AS40

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

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 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.

DATES: Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 8, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1631–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–1631–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–1631–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:

Donta Henson, (410) 786–1947 for any physician payment issues not identified below.

Gail Addis, (410) 786–4522, for issues related to the refinement panel.

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology, impacts, conversion factors, target, and phase-in provisions.

Jessica Bruton, (410) 786–5991, for issues related to potentially misvalued code lists.

Geri Mondowney, (410) 786–4584, for issues related to geographic practice cost indices and malpractice RVUs.

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

Ann Marshall, (410) 786–3059, for issues related to advance care planning, and for primary care and care management services.

Michael Soracoe, (410) 786–6312, for issues related to the valuation and coding of the global surgical packages.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy.

Regina Walker-Wren, (410) 786–9160, for issues related to the ''incident to'' proposals.

Lindsey Baldwin, (410) 786–1694, for issues related to valuation of moderate sedation and colonoscopy services and portable x-ray transportation fees.

Emily Yoder, (410) 786–1804, for issues related to valuation of radiation treatment services.

Amy Gruber, (410) 786–1542, for issues related to ambulance payment policy.

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

Simone Dennis, (410) 786–8409, for issues related to rural health clinics HCPCS reporting.

Edmund Kasaitis (410) 786–0477, for issues related to Part B drugs, biologicals, and biosimilars.

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

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system and the merit-based incentive payment system.

Alexandra Mugge (410) 786–4457, for issues related to EHR Incentive Program.

Sarah Arceo, (410) 786–2356) or Patrice Holtz, (410–786–5663) for issues related to EHR Incentive Program-CPC initiative and meaningful use aligned reporting.

Christiane LaBonte, (410) 786–7237, for issues related to comprehensive primary care initiative.

Rabia Khan, (410) 786–9328 or Terri Postma, (410) 786–4169, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786–3232, or Sabrina Ahmed (410) 786–7499, for issues related to value-based Payment Modifier and Physician Feedback Program.

Frederick Grabau, (410) 786–0206, for issues related to changes to opt-out regulations.

Lisa Ohrin Wilson (410) 786–8852, 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:

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)
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
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 2014 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
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
EHR Electronic health record
E/M Evaluation and management
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
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
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
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
MSSP Medicare Shared Savings Program
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
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PT Physical therapy
PY Performance year
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 2016 PFS proposed rule, refer to item CMS–1631–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 Donta Henson at (410) 786–1947.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary 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 proposed changes would be applicable to services furnished in CY 2016.

2. Summary of the Major Provisions

The Social Security Act (the Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act 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 establish RVUs for CY 2016 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.
- Advance Care Planning Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- ''Incident to'' policy.
- Portable X-Ray Transportation Fee.
- Updating the Ambulance Fee Schedule regulations.
- Changes in Geographic Area Delineations for Ambulance Payment.
- Chronic Care Management Services for RHCs and FQHCs.
- HCPCS Coding for RHCs.
- Payment to Grandfathered Tribal FQHCs that were Provider-Based Clinics on or before April 7, 2000.
- Payment for Biosimilars under Medicare Part B.
- Physician Compare Web site.
- Physician Quality Reporting System.
- Medicare Shared Savings Program.
- Electronic Health Record (EHR) Incentive Program.
- Value-Based Payment Modifier and the Physician Feedback Program.

3. Summary of Costs and Benefits

The Act 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 proposed changes would affect the specialty distribution of Medicare expenditures. When considering the combined impact of work, PE, and MP RVU changes, the projected payment impacts are 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 VII. of this proposed rule.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of 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.

b. Practice Expense RVUs

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

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

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

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

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

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

c. Malpractice RVUs

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

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:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU MP x GPCI MP)] x 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 assure 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 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) 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 also 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, 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 originally applied the target to CYs 2017 through 2020 and set the target amount to 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years.

More recently, section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014) accelerated the application of the target, amending section 1848(c)(2)(O) of the Act to specify that targets would apply for CYs 2016, 2017, and 2018 and set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. The implementation of the target legislation is discussed in section II.F. of this proposed rule.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. Although section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017, section 202 of the ABLE Act now requires the phase-in to begin in CY 2016. The implementation of the phase-in legislation is discussed in section II.G. of this proposed rule.

Section 218(a) of the PAMA adds a new section 1834(p) to the statute. Section 1834(p) requires reductions in payment for the technical component (TC) (and the TC of the global fee) of the PFS service and in the hospital OPPS payment (5 percent in 2016, and 15 percent in 2017 and subsequent years) for computed tomography (CT) services (identified as of January 1, 2014 by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574, and succeeding codes) furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' The implementation of section 218(a) of the PAMA is discussed in section II.H. of this proposed rule.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) makes several changes to the statute, including but not limited to:

(1) Repealing the sustainable growth rate (SGR) update methodology for physicians' services.

(2) Revising the PFS update for 2015 and subsequent years.

(3) Establishing a Merit-based Incentive Payment System (MIPS) under which eligible professionals (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive annual payment increases or decreases based on their performance in a prior period. These and other MACRA provisions are discussions in various sections of this proposed rule. Please refer to the table of contents for the location of the various MACRA provision discussions.

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 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).

For CY 2016, we have incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. We are proposing to use a proxy PE/HR value for interventional cardiology, 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. The proposed change is reflected in the ''PE/HR'' file available on the CMS Web site under the supporting data files for the CY 2016 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

c. Allocation of PE to Services

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

(1) Direct Costs

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

(2) Indirect Costs

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 use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, 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 add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had 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 incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(4) 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. Because 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 in a facility, 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.

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

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

(6) 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).

(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. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. Under our current methodology, we first multiply the current year's conversion factor by the product of the current year's PE RVUs and utilization for each service to arrive at the aggregate pool of total PE costs (Step 2a). We then calculate the average direct percentage of the current pool of PE RVUs (using a weighted average of the survey data for the specialties that furnish each service (Step 2b).) We then multiply the result of 2a by the result of 2b to arrive at the aggregate pool of direct PE costs for the current year. For CY 2016, we are proposing a technical improvement to step 2a of this calculation. In place of the step 2a calculation described above, we propose to 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. Historically, in allowing the current PE RVUs to determine the size of the base PE pool in the PE methodology, we have assumed that the relationship of PE RVUs to work RVUs is constant from year to year. Since this is not ordinarily the case, by not considering the proposed aggregate work RVUs in determining the size of the base PE pool, we have introduced some minor instability from year to year in the relative shares of work, PE, and MP RVUs. While this proposed modification would result in greater stability in the relationship among the work and PE RVU components in the aggregate, we do not anticipate it will affect the distribution of PE RVUs across specialties. The PE RVUs in addendum B of this proposed rule with comment period reflect this proposed refinement to the PE methodology.

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 adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling 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.

Historically, we have used the specialties that furnish the service in the most recent full year of Medicare claims data (crosswalked to the current year set of codes) to determine which specialties furnish individual procedures. For example, for CY 2015 ratesetting, we used the mix of specialties that furnished the services in the CY 2013 claims data to determine the specialty mix assigned to each code. While we believe that there are clear advantages to using the most recent available data in making these determinations, we have also found that using a single year of data contributes to greater year-to-year instability in PE RVUs for individual codes and often creates extreme, annual fluctuations for low-volume services, as well as delayed fluctuations for some services described by new codes once claims data for those codes becomes available.

We believe that using an average of the three most recent years of available data may increase stability of PE RVUs and mitigate code-level fluctuations for both the full range of PFS codes, and for new and low-volume codes in particular. Therefore, we are proposing to refine this step of the PE methodology to use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. The PE RVUs in Addendum B of the CMS Web site reflect this proposed refinement to the PE methodology.

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 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 Table 1, 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 2a (as calculated with the proposed change) 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 6 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 results of Step 18 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs, consistent with the proposed changes in Steps 2 and 9. This final BN adjustment is required to redistribute RVUs from step 18 to all PE RVUs in the PFS, and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but we note that all specialties are included for purposes of calculating the final BN adjustment. (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.
62	Co-surgeons	62.5%	50%.

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

Modifier	Description	Volume adjustment	Time adjustment
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 with comment period.

(7) 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. We also direct the reader to section II.5.b of this proposed rule for a discussion of our proposed change in the utilization rate assumption for the linear accelerator used in furnishing radiation treatment services.

Maintenance: This factor for maintenance was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). Several stakeholders have suggested that this maintenance factor assumption should be variable, similar to other assumptions in the equipment cost per minute calculation. In CY 2015 rulemaking, we solicited comments regarding the availability of reliable data on maintenance costs that vary for particular equipment items. We received several comments about variable maintenance costs, and in reviewing the information offered in those comments, it is clear that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment. However, based on our review of comments, we have been unable to identify a systematic way of varying the maintenance cost assumption relative to the price or useful life of equipment. Therefore, in order to accommodate a variable, as opposed to a standard, maintenance rate within the equipment cost per minute calculation, we believe we would have to gather and maintain valid data on the maintenance costs for each equipment item in the direct PE input database, much like we do for price and useful life.

Given our longstanding difficulties in acquiring accurate pricing information for equipment items, we are seeking comment on whether adding another item-specific financial variable for equipment costs will be likely to increase the accuracy of PE RVUs across the PFS. We note that most of the information for maintenance costs we have received is for capital equipment, and for the most part, this information has been limited to single invoices. Like the invoices for the equipment items themselves, we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical costs for all of the same reasons we have discussed in previous rulemaking. We note that some commenters submitted high-level summary data from informal surveys but we currently have no means to validate that data. Therefore, we continue to seek a source of publicly available data on actual maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing PE RVUs.

Interest Rate: In the CY 2013 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.)

TABLE 3—SBA MAXIMUM INTEREST RATES

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

TABLE 4—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est non-facility	33533 CABG, arterial, single facility	71020 chest x-ray nonfacility	71020–TC chest x-ray, nonfacility	71020–26 chest x-ray, nonfacility	93000 ECG, complete, non-facility	93005 ECG, tracing non-facility	93010 ECG, report non-facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0	5.1	5.1	0
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	0.53	0.53	0	1.19	1.19	0
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.08	7.08	0	0.09	0.09	0
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	85.45	13.36	13.36	0	6.38	6.38	0
(5) Direct adjustment (Dir. Adj.)	Steps 2–4	See footnote*		0.6003	0.6003	0.6003	0.6003	0.6003	0.6003	0.6003	0.6003
(6) Adjusted Labor	Steps 2–4	=Labor * Dir Adj.	=(1)*(5)	8	46.53	3.45	3.45	0	3.06	3.06	0
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj.	=(2)*(5)	1.79	4.41	0.32	0.32	0	0.72	0.72	0
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj.	=(3)*(5)	0.10	0.35	4.25	4.25	0	0.05	0.05	0
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	9.89	51.29	8.02	8.02	0	3.83	3.83	0
(10) Conversion Factor (CF)	Step 5	PFS		35.9335	35.9335	35.9335	35.9335	35.9335	35.9335	35.9335	35.9335
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF.	=(6)/(10)	0.22	1.3	0.1	0.1	0	0.09	0.09	0
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF.	=(7)/(10)	0.05	0.12	0.01	0.01	0	0.02	0.02	0
(13) Adj. equipment cost converted.	Step 5	=(Eqp * Dir Adj)/CF.	=(8)/(10)	0	0.01	0.12	0.12	0	0	0	0
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.28	1.43	0.22	0.22	0	0.11	0.11	0
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0	0.22	0.17	0	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.25	0.17	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind_pct	Steps 6,7	Surveys		0.75	0.83	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)
(19) Ind. Alloc.(1st part)	Step 8		See 18	0.83	6.75	0.54	0.54	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd part).	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.32	0.1	0.22	0.26	0.09	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8		=(19)+(21)	1.8	40.50	0.86	0.64	0.22	0.52	0.35	0.17
(23) Indirect Adjustment (Ind. Adj.).	Steps 9–11	See Footnote**.		0.3811	0.3811	0.3811	0.3811	0.3811	0.3811	0.3811	0.3811
(24) Adjusted Indirect Allocator	Steps 9–11	=Ind Alloc * Ind Adj.		0.69	15.43	0.33	0.24	0.08	0.2	0.13	0.06
(25) Ind. Practice Cost Index (IPCI).	Steps 12–16.			1.07	0.76	0.98	0.98	0.98	0.9	0.9	0.9
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI.	=(24)*(25)	0.73	11.68	0.32	0.24	0.08	0.18	0.12	0.06
(27) Final PE RVU	Step 18	=(Adj Dir + Adj Ind) * Other Adj.	=((14)+(26)) * Other Adj).	1.01	13.15	0.54	0.46	0.08	0.28	0.23	0.06

Notes: PE RVUs above (row 27), may not match Addendum B due to rounding.

The use of any particular conversion factor (CF) in the table to illustrate the PE Calculation has no effect on the resulting RVUs.

*The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [step2]/[step3]; **The indirect adj =[current pe rvus * avg ind pct]/[sum of ind allocators]=[step9]/[step10]

c. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2016 proposals related to particular PE inputs. The proposed direct PE inputs are included in the proposed CY 2016 direct PE input database, which is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period 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 CY 2015 rulemaking, 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 list of codes since these items are 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 are now typically used in furnishing imaging services. However, since we did not receive any invoices for the PACS system, we were unable to determine the appropriate pricing to use for the inputs. For CY 2015, we proposed, and 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. We used the current 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. Some of these stakeholders submitted information that included prices for items clearly categorized as indirect costs within the established PE methodology and equivalent to the storage mechanisms for film. Additionally, some of the invoices we received included other products (like training and maintenance costs) in addition to the equipment items, and there was no distinction on these invoices between the prices for the equipment items themselves and the related services. However, we did receive invoices from one stakeholder that facilitated a proposed price update for the PACS workstation. Therefore, we are proposing to update the price for the PACS workstation to $5,557 from the current price of $2,501 since the latter price was based on the proxy item and the former based on submitted invoices. The PE RVUs in Addendum B on the CMS Web site reflect the updated price.

In addition to the workstation used by the clinical staff acquiring the images and furnishing the technical component of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the professional component of many of these services. As we stated in the CY 2015 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 professional component 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. Given that many of these services are reported globally in the nonfacility setting, we believe it may be appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on our established methodology, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code. We are seeking comment 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.

Another stakeholder expressed concern about the changes in direct PE inputs for CPT code 76377, (3D radiographic procedure with computerized image post-processing), that were proposed and finalized in CY 2015 rulemaking as part of the film to digital change. Based on a recommendation from the RUC, we removed the input called ''computer workstation, 3D reconstruction CT–MR'' from the direct PE input database and assigned the associated minutes to the proxy for the PACS workstation. We are seeking comment from stakeholders, including the RUC, about whether or not the PACS workstation used in in imaging codes is the same workstation that is used in the postprocessing described by CPT code 76377, or if more specific workstation should be incorporated in the direct PE input database . . .

(2) Standardization of Clinical Labor Tasks

As we noted in PFS rulemaking for CY 2015, 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 pre-service, service, and post-service 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 will facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It will 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 pre-service time packages. We believe such standards will 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.

While this work is not yet complete, we anticipate completing it in the near future. 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 PFS rulemaking for CY 2015, 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 the minutes for each code 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, 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 for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the database facilitate our ability to adjust time for existing services. Therefore, we are seeking comment on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology, which are listed in Table 5. We note that the application of any standardized times we adopt for clinical labor tasks to codes that are not being reviewed in this proposed rule would be considered for possible inclusion in future notice and comment rulemaking.

TABLE 5—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL 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
Technologist QC's * images in PACS, checking for all images, reformats, and dose page	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

*This clinical labor task is listed as it appears on the ''PE worksheets.'' QC refers to quality control, which we understand to mean the verification of the image using the PACS workstation.

(b) Pathology Clinical Labor Tasks

As with the clinical labor tasks associated with digital imaging, many of the specialized clinical labor tasks associated with pathology services do not have consistent times across those codes. In reviewing the recommendations for pathology services, we have not identified information that suggests that the inconsistencies reflect 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 specificity with which they are described.

We have therefore developed proposed standard times that we have used in proposing direct PE inputs. These times are based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We have listed these proposed standard times in Table 6. For services reviewed for CY 2016, in cases where the RUC-recommended times differed from these standards, we have refined the time for those tasks to align with the values in Table 6. We seek comment on whether these standard times accurately reflect the typical time it takes to perform these clinical labor tasks when furnishing pathology services.

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

Clinical Labor Task	Standard clinical labor time
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
Assist pathologist with gross specimen examination	3
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
Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer	1
Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling	13
Load specimen into flow cytometer, run specimen, monitor data acquisition and data modeling, and unload flow cytometer	7
Preparation: labeling of blocks and containers and document location and processor used	0.5
Prepare automated stainer with solutions and load microscopic slides	4
Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician	0.5
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	1
Print out histograms, assemble materials with paperwork to pathologists. Review histograms and gating with pathologist.	2
Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit, including muscle biopsy clamp as needed. Review with sender instructions for preservation of specimen integrity and return arrangements. Contact courier and arrange delivery to referring laboratory/facility	5
Register the patient in the information system, including all demographic and billing information.	4
Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination)	3

(c) Clinical Labor Task: ''Complete Botox Log''

In the process of improving the level of detail in the direct PE input database by including the minutes assigned for each clinical labor task, we noticed that there are several codes with minutes assigned for the clinical labor task called ''complete botox log.'' We do not believe the completion of such a log is a direct resource cost of furnishing a medically reasonable and necessary physician's service for a Medicare beneficiary. Therefore, we are proposing to eliminate the minutes assigned for the task ''complete botox log'' from the direct PE input database. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

(3) Clinical Labor Input Inconsistencies

Subsequent to the publication of the CY 2015 PFS final rule with comment period, stakeholders alerted us to several clerical inconsistencies in the clinical labor nonfacility intraservice time for several vertebroplasty codes with interim final values for CY 2015, based on our understanding of RUC recommended values. We are proposing to correct these inconsistencies in the CY 2016 proposed direct PE input database to reflect the RUC recommended values, without refinement, as stated in the CY 2015 PFS final rule with comment period. The CY 2015 interim final direct PE inputs for these codes are displayed on the CMS Web site under downloads 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.html.* For CY 2016, we are proposing the following adjustments. For CPT codes 22510 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic) and 22511 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral), a value of 45 minutes for labor code L041B (''Radiologic Technologist'') were are proposing to assign for the ''assist physician'' task and a value of 5 minutes for labor code L037D (''RN/LPN/MTA'') for the ''Check dressings & wound/home care instructions/coordinate office visits/prescriptions'' task. For CPT code 22514 (percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar), we are proposing to adjust the nonfacility intraservice time to 50 minutes for L041B, 50 minutes for L051A (''RN''), 38 minutes for a second L041B, and 12 minutes for L037D. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the inputs displayed in the CY 2016 direct PE input database.

(4) Freezer

We identified several pathology codes for which equipment minutes are assigned to the item EP110 ''Freezer.'' Minutes are only allocated to particular equipment items when those items cannot be used in conjunction with furnishing services to another patient at the same time. We do not believe that minutes should be allocated to items such as freezers since the storage of any particular specimen or item in a freezer for any given period of time would be unlikely to make the freezer unavailable for storing other specimens or items. Instead, we propose to classify the freezer as an indirect cost because we believe that would be most consistent with the principles underlying the PE methodology since freezers can be used for many specimens at once. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

(5) Updates to Price for Existing Direct 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. During 2014, we received a request to update the price of supply item ''antigen, mite'' (SH006) from $4.10 per test to $59. In reviewing the request, it is evident that the requested price update does not apply to the SH006 item but instead represents a different item than the one currently included as an input in CPT code 86490 (skin test, coccidioidomycosis). Therefore, rather than changing the price for SH006 that is included in several codes, we are proposing to create a new supply code for Spherusol, valued at $590 per 1 ml vial and $59 per test, and to include this new item as a supply for 86490 instead of the current input, SH006. We also received a request to update the price for EQ340 (Patient Worn Telemetry System) used only in CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care.) The requestor noted that we had previously proposed and finalized a policy to remove wireless communication and delivery costs related to the equipment item that had previously been included in the direct PE input database as supply items. The requestor asked that we alter the price of the equipment from $21,575 to $23,537 to account for the equipment costs specific to the patient-worn telemetry system.

We have considered this request in the context of the unique nature of this particular equipment item. This equipment item is unique in several ways, including that it is used continuously 24 hours per day and 7 days per week for an individual patient over several weeks. It is also unique in that the equipment is primarily used outside of a healthcare setting. Within our current methodology, we currently account for these unique properties by calculating the per minute costs with different assumptions than those used for most other equipment by increasing the number of hours the equipment is available for use. Therefore, we also believe it would be appropriate to incorporate other unique aspects of the operating costs of this item in our calculation of the equipment cost per minute. We believe the requestor's suggestion to do so by increasing the price of the equipment is practicable and appropriate. Therefore, we are proposing to change the price for EQ340 (Patient Worn Telemetry System) to $23,537. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

For CY 2015, we received a request to update the price for supply item ''kit, HER–2/neu DNA Probe'' (SL196) from $105 to $144.50. Accordingly, we proposed to update the price to $144.50. In the CY 2015 final rule with comment period, we indicated that we obtained new information suggesting that further study of the price of this item was necessary before proceeding to update

the input price. We obtained pricing information readily available on the Internet that indicated a price of $94 for this item for a particular hospital. Subsequent to the CY 2015 final rule with comment period, stakeholders requested that we use the updated price of $144.50. One stakeholder suggested that the price of $94 likely reflected discounts for volume purchases not received by the typical laboratory. We are seeking comment on how to consider the higher-priced invoice, which is 53 percent higher than the price listed, relative to the price currently in the direct PE database. Specifically, we are seeking information on the price of the disposable supply in the typical case of the service furnished to a Medicare beneficiary, including, based on data, whether the typical Medicare case is furnished by an entity likely to receive a volume discount.

(6) Typical Supply and Equipment Inputs for Pathology Services

In reviewing public comments in response to the CY 2015 PFS final rule with comment period, we re-examined issues around the typical number of pathology tests furnished at once. In the CY 2013 final rule with comment period (77 FR 69074), we noted that the number of blocks assumed for a particular code significantly impacts the assumed clinical labor, supplies, and equipment for that service. We indicated that we had concerns that the assumed number of blocks was inaccurate, and that we sought corroborating, independent evidence that the number of blocks assumed in the current direct PE input recommendations is typical. We note that, given the high volume of many pathology services, these assumptions have a significant impact on the PE RVUs for all other PFS services. We refer readers to section II.I.5.d where we detail our concerns about the lack of information regarding typical batch size and typical block size for many pathology services and solicit stakeholder input on approaches to obtaining accurate information that can facilitate our establishing payment rates that best reflect the relative resources involved in furnishing the typical service, for both pathology services in particular and more broadly for services across the PFS.

d. Developing Nonfacility Rates

We note that not all PFS services are priced in the nonfacility setting, but as medical practice changes, we routinely develop nonfacility prices for particular services when they can be furnished outside of a facility setting. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition.

(1) Request for Information on Nonfacility Cataract Surgery

Cataract surgery generally has been performed in an ambulatory surgery center (ASC) or a hospital outpatient department (HOPD). Therefore, CMS has not assigned nonfacility PE RVUs under the PFS for cataract surgery. According to Medicare claims data, there are a relatively small number of these services furnished in nonfacility settings. Except in unusual circumstances, anesthesia for cataract surgery is either local or topical/intracameral. Advancements in technology have significantly reduced operating time and improved both the safety of the procedure and patient outcomes. We believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. Cataract surgery patients require a sterile surgical suite with certain equipment and supplies that we believe could be a part of a nonfacility-based setting that is properly constructed and maintained for appropriate infection prevention and control.

We believe that there are potential advantages for all parties to furnishing appropriate cataract surgery cases in the nonfacility setting. Cataract surgery has been for many years the highest volume surgical procedure performed on Medicare beneficiaries. For beneficiaries, cataract surgery in the office setting might provide the additional convenience of receiving the preoperative, operative, and post-operative care in one location. It might also reduce delays associated with registration, processing, and discharge protocols associated with some facilities. Similarly, it might provide surgeons with greater flexibility in scheduling patients at an appropriate site of service depending on the individual patient's needs. For example, routine cases in patients with no comorbidities could be performed in the nonfacility surgical suite, while more complicated cases (for example, pseudoexfoliation) could be scheduled in the ASC or HOPD. In addition, furnishing cataract surgery in the nonfacility setting could result in lower Medicare expenditures for cataract surgery if the nonfacility payment rate were lower than the sum of the PFS facility payment rate and the payment to either the ASC or HOPD.

We are seeking comments from ophthalmologists and other stakeholders on office-based surgical suite cataract surgery. In addition, we are soliciting comments from the RUC and other stakeholders on the direct practice expense inputs involved in furnishing cataract surgery in the nonfacility setting in conjunction with our consideration of information regarding the possibility of developing nonfacility PE RVUs for cataract surgery. We understand that cataract surgery generally requires some standard equipment and supplies (for example; phacoemulsification machine, surgical pack, intraocular lenses (IOL), etc.) that would be incorporated as direct PE inputs in calculating nonfacility PE RVUs.

(2) Direct PE Inputs for Functional Endoscopic Sinus Surgery Services

A stakeholder indicated that due to changes in technology and technique, several codes that describe endoscopic sinus surgeries can now be furnished in the nonfacility setting. According to Medicare claims data, there are a relatively small number of these services furnished in nonfacility settings. These CPT codes are 31254 (Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)), 31255 (Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)), 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy;), 31267 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus), 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus), 31287 (Nasal/sinus endoscopy, surgical, with sphenoidotomy;), and 31288 (Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus). We are seeking input from stakeholders, including the RUC, about the appropriate direct PE inputs for these services.

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 comprised of three components: work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. 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 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).

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 five-year review of MP RVUs (for example, effective CY 2016 through CY 2019, assuming that the next review of MP RVUs occurs for CY 2020) are 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 value (or, if greater, 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 is 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.

For CY 2016, we propose to continue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we include proposed work values and PE inputs in the proposed rule, we will also publish the proposed MP crosswalks used to determine their MP RVUs in the proposed rule. The MP crosswalks for those new and revised codes will be subject to public comment and finalized in the CY 2016 PFS final rule. The MP crosswalks for new and revised codes with interim final values established in the CY 2016 final rule will be implemented for CY 2016 and subject to public comment. They will then be finalized in the CY 2017 PFS final rule with comment period.

2. Proposed Annual Update of MP RVUs

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a process to consolidate the five-year reviews of physician work and PE RVUs with our annual review of potentially misvalued codes. We discussed the exclusion of MP RVUs from this process at the time, and we stated that, since it is not feasible to obtain updated specialty level MP insurance premium data on an annual basis, we believe the comprehensive review of MP RVUs should continue to occur at 5-year intervals. In the CY 2015 PFS proposed rule (79 FR 40349 through 40355), we stated that there are two main aspects to the update of MP RVUs: (1) Recalculation of specialty risk factors based upon updated premium data; and (2) recalculation of service level RVUs based upon the mix of practitioners providing the service. In the CY 2015 PFS final rule with comment period (79 FR 67596), in response to several stakeholders' comments, we stated that we would address potential changes regarding the frequency of MP RVU updates in a future proposed rule. For CY 2016, we are proposing to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services, and to adjust MP RVUs for risk. Under this approach, the specialty-specific risk factors would continue to be updated every five years using updated premium data, but would remain unchanged between the 5-year reviews. However, in an effort to ensure that MP RVUs are as current as possible, our proposal would involve recalibrating all MP RVUs on an annual basis to reflect the specialty mix based on updated Medicare claims data. Since under this proposal, we would be recalculating the MP RVUs annually, we are also proposing to maintain the relative pool of MP RVUs from year to year; this will preserve the relative weight of MP RVUs to work and PE RVUs. We are proposing to calculate the current pool of MP RVUs by using a process parallel to the one we use in calculating the pool of PE RVUs. (We direct the reader to section II.2.b.(6) for detailed description of that process, including a proposed technical revision for 2016.) To determine the specialty mix assigned to each code, we are also proposing to use the same process used in the PE methodology, described in section II.2.b.(6) of this proposed rule. We note that for CY 2016, we are proposing to modify the specialty mix assignment methodology to use an average of the 3 most recent years of available data instead of a single year of data as is our current policy. We anticipate that this change will increase the stability of PE and MP RVUs and mitigate code-level fluctuations for all services paid under the PFS, and for new and low-volume codes in particular. We are also proposing to no longer apply the dominant specialty for low volume services, because the primary rationale for the policy has been mitigated by this proposed change in methodology. However, we are not proposing to adjust the code-specific overrides established in prior rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service. We believe that these proposed changes will serve to balance the advantages of using annually updated information with the need for year-to-year stability in values. We seek comment on both aspects of the proposal: updating the specialty mix for MP RVUs annually (while continuing to update specialty-specific risk factors every 5 years using updated premium data); and using the same process to determine the specialty mix assigned to each code as is used in the PE methodology, including the proposed modification to use the most recent 3 years of claims data. We also seek comment on whether this approach will be helpful in addressing some of the concerns regarding the calculation of MP RVUs for services with low volume in the Medicare population, including the possibility of limiting our use of code-specific overrides of the claims data.

We are also proposing an additional refinement in our process for assigning MP RVUs to individual codes. Historically, we have used a floor of 0.01 MP RVUs for all nationally-priced PFS codes. This means that even when the code-level calculation for the MP RVU falls below 0.005, we have rounded to 0.01. In general, we believe this approach accounts for the minimum MP costs associated with each service furnished to a Medicare beneficiary. However, in examining the calculation of MP RVUs, we do not believe that this floor should apply to add-on codes. Since add-on codes must be reported with another code, there is already an MP floor of 0.01 that applies to the base code, and therefore, to each individual service. By applying the floor to add-on codes, the current methodology practically creates a 0.02 floor for any service reported with one add-on code, and 0.03 for those with 2 add-on codes, etc. Therefore, we are proposing to maintain the 0.01 MP RVU floor for all nationally-priced PFS services that are described by base codes, but not for add-on codes. We will continue to calculate, display, and make payments that include MP RVUs for

add-on codes that are calculated to 0.01 or greater, including those that round to 0.01. We are only proposing to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005.

We will continue to study the appropriate frequency for collecting and updating premium data and will address any further proposed changes in future rulemaking.

3. MP RVU Update for Anesthesia Services

In the CY 2015 PFS proposed rule (79 FR 40354 through 40355), we did not include an adjustment under the anesthesia fee schedule to reflect updated MP premium information, and stated that we intended to propose an anesthesia adjustment for MP in the CY 2016 PFS proposed rule. We also solicited comments regarding how to best reflect updated MP premium amounts under the anesthesiology fee schedule.

As we previously explained, anesthesia services under the PFS are paid based upon a separate fee schedule, so routine updates must be calculated in a different way than those for services for which payment is calculated based upon work, PE, and MP RVUs. To apply budget neutrality and relativity updates to the anesthesiology fee schedule, we typically develop proxy RVUs for individual anesthesia services that are derived from the total portion of PFS payments made through the anesthesia fee schedule. We then update the proxy RVUs as we would the RVUs for other PFS services and adjust the anesthesia fee schedule conversion factor based on the differences between the original proxy RVUs and those adjusted for relativity and budget neutrality.

We believe that taking the same approach to update the anesthesia fee schedule based on new MP premium data is appropriate. However, because work RVUs are integral to the MP RVU methodology and anesthesia services do not have work RVUs, we decided to seek potential alternatives prior to implementing our approach in conjunction with the proposed CY 2015 MP RVUs based on updated premium data. One commenter supported the delay in proposing to update the MP for anesthesia at the same time as updating the rest of the PFS, and another commenter suggested using mean anesthesia MP premiums per provider over a 4 or 5 year period prorated by Medicare utilization to yield the MP expense for anesthesia services; no commenters offered alternatives to calculating updated MP for anesthesia services. The latter suggestion might apply more broadly to the MP methodology for the PFS and does not address the methodology as much as the data source.

We continue to believe that payment rates for anesthesia should reflect MP resource costs relative to the rest of the PFS, including updates to reflect changes over time. Therefore, for CY 2016, in order to appropriately update the MP resource costs for anesthesia, we are proposing to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the five year review. To determine the appropriate adjustment, we calculated imputed work RVUs and MP RVUs for the anesthesiology fee schedule services using the work, PE, and MP shares of the anesthesia fee schedule. Again, this is consistent with our longstanding approach to making annual adjustments to the PE and work RVU portions of the anesthesiology fee schedule. To reflect differences in the complexity and risk among the anesthesia fee schedule services, we multiplied the service-specific risk factor for each anesthesia fee schedule service by the CY 2016 imputed proxy work RVUs and used the product as the updated raw proxy MP RVUs for each anesthesia service for CY 2016. We then applied the same scaling adjustments to these raw proxy MP RVUs that we apply to the remainder of the PFS MP RVUs. Finally, we calculated the aggregate difference between the 2015 proxy MP RVUs and the proxy MP RVUs calculated for CY 2016. We then adjusted the portion of the anesthesia conversion factor attributable to MP proportionately; we refer the reader to section VI.C. of this proposed rule for the Anesthesia Fee Schedule Conversion Factors for CY 2016. We are inviting public comments regarding this proposal.

4. MP RVU Methodology Refinements

In the CY 2015 PFS final rule with comment period (79 FR 67591 through 67596), we finalized updated MP RVUs that were calculated based on updated MP premium data obtained from state insurance rate filings. The methodology used in calculating the finalized CY 2015 review and update of resource-based MP RVUs largely paralleled the process used in the CY 2010 update. We posted our contractor's report, ''Final Report on the CY 2015 Update of Malpractice RVUs'' on the CMS Web site. It is also located under the supporting documents section of the CY 2015 PFS final rule with comment period located at *http://www.cms.gov/PhysicianFeeSched/*. A more detailed explanation of the 2015 MP RVU update can be found in the CY 2015 PFS proposed rule (79 FR 40349 through 40355).

In the CY 2015 PFS proposed rule, we outlined the steps for calculating MP RVUs. In the process of calculating MP RVUs for purposes of this proposed rule, we have identified a necessary refinement to way we have calculated Step 1, which involves computing a preliminary national average premium for each specialty, to align the calculations within the methodology to the calculations described within the aforementioned contractor's report. Specifically, in the calculation of the national premium for each specialty (refer to equations 2.3, 2.4, 2.5 in the aforementioned contractor's report), we calculate a weighted sum of premiums across areas and divide it by a weighted sum of MP GPCIs across areas. The calculation currently takes the ratio of sums, rather than the weighted average of the local premiums to the MP GPCI in that area. Instead, we are proposing to update the calculation to use a price-adjusted premium (that is, the premium divided by the GPCI) in each area, and then taking a weighted average of those adjusted premiums. The CY 2016 PFS proposed rule MP RVUs were calculated in this manner.

Additionally, in the calculation of the national average premium for each specialty as discussed above, our current methodology used the total RVUs in each area as the weight in the numerator (that is, for premiums), and total MP RVUs as the weights in the denominator (that is, for the MP GPCIs). After further consideration, we believe that the use of these RVU weights is problematic. Use of weights that are central to the process at hand presents potential circularity since both weights incorporate MP RVUs as part of the computation to calculate MP RVUs. The use of different weights for the numerator and denominator introduces potential inconsistency. Instead, we believe that it would be better to use a different measure that is independent of MP RVUs and better represents the reason for weighting. Specifically, we are proposing to use area population as a share of total U.S. population as the weight. The premium data are for all MP premium costs, not just those associated with Medicare patients, so we believe that the distribution of the population does a better job of capturing the role of each area's premium in the ''national'' premium for each specialty than our previous Medicare-specific measure. Use of population weights also avoids the potential problems of circularity and inconsistency.

The CY 2016 PFS proposed MP RVUs, as displayed in Addendum B of this proposed rule, reflect MP RVUs calculated following our established methodology, with the inclusion of the proposals and refinements described above.

C. 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 I.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 to establish relative values for these codes. We may also consider analyses of work time, work RVUs, or direct practice expense (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. 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, in addition to requiring us to take into account the results of consultations with organizations representing physicians who furnish the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs. We discuss these methodologies as applied to particular codes in section I.B. of this proposed rule.

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 PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high 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 PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we 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 1,560 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 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 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, we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 (76 FR 32410). In the CY 2013 final rule with comment period, we identified as potentially misvalued Harvard-valued services with annual allowed charges that total at least $10,000,000. In addition to the Harvard-valued codes, in the CY 2013 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 and listed work time).

In the CY 2014 final rule with comment period, we finalized for review a list of potentially misvalued services. We included on the list for review ultrasound guidance codes that had longer procedure times than the typical procedure with which the code is billed to Medicare. We also finalized our proposal to replace missing post-operative hospital E/M visit information and work time for approximately 100 global surgery codes. In CY 2014, we also considered a proposal to limit Medicare PFS payments for services furnished in a non-facility setting when the PFS payment would exceed the combined Medicare payment made to the practitioner under the PFS and facility payment made to either the ASC or hospital outpatient. Based upon extensive public comment we did not finalize this proposal.

In the CY 2015 final rule with comment period, we finalized a list of potentially misvalued services. The potentially misvalued codes list included the publicly nominated CPT code 41530; two neurostimulator implantation codes, CPT 64553 and 64555; four epidural injection codes, CPT 62310, 62311, 62318 and 62319; three breast mammography codes, CPT 77055, 77056 and 77057; an abdominal aortic aneurysm ultrasound screening code, HCPCS G0389; a prostate biopsy code, G0416; and an obesity behavioral group counseling code, HCPCS G0473. We also finalized our ''high expenditure services across specialty'' screen as a tool to identify potentially misvalued codes though we did not finalize the particular list of codes identified in that rule as potentially misvalued. In CY 2015, we also considered and finalized a proposal addressing the valuation and coding of global surgical packages, which would revalue and transition 10 and 90-day global codes to 0-day codes. We also sought comment on approaches to revalue services that included moderate sedation as an inherent part of furnishing the procedure.

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 is 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 collect time data from several practices for services selected by the contractor in consultation with CMS. Urban Institute has used a variety of approaches to develop objective time estimates, depending on the type of service. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and the potential implications for work and the ratio of work to time. Urban Institute has prepared an interim report, ''Development of a Model for the Valuation of Work Relative Value Units,'' which discusses the challenges encountered in collecting objective time data and offers some thoughts on how these can be overcome. This interim report is posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-UrbanInterimReport.pdf.* A final report will be available once the project is complete.

The second contract is with the RAND Corporation, which is using 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 on the CMS Web site under downloads 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.*

4. CY 2016 Identification of Potentially Misvalued Services for Review

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule with comment period, we finalized a process for the public to nominate potentially misvalued codes (76 FR 73058). The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may

include, but are not limited to, the following:

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

After we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code.

During the comment period on the CY 2015 proposed rule and final rule with comment period, we received nominations and supporting documentation for three codes to be considered as potentially misvalued codes. We evaluated the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued.

CPT Code 36516 (Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion) was nominated for review as potentially misvalued. The nominator stated that CPT code 36516 is misvalued because of incorrect direct and indirect PE inputs and an incorrect work RVU. Specifically, the nominator stated that the direct supply costs failed to include an $18 disposable bag and the $37 cost for biohazard waste disposal of the post-treatment bag, and the labor costs associated with nursing being inaccurate. The nominator also stated that the overhead expenses associated with this service were unrealistic and that the current work RVU undervalues a physician's time and expertise. We are proposing this code as a potentially misvalued code. We note that we established a policy in CY 2011 to consider biohazard bags as an indirect expense, and not as a direct PE input (75 FR 73192).

CPT Codes 52441 (Cystourethroscopy with insertion of permanent adjustable transprostatic implant; single implant) and 52442 (Cystourethroscopy with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant) were nominated for review as potentially misvalued. The nominator stated that the costs of the direct practice expense inputs were inaccurate, including the cost of the implant. We are proposing these codes as potentially misvalued codes.

b. Electronic Analysis of Implanted Neurostimulator (CPT Codes 95970–95982)

All of the inputs for CPT codes 95971 (Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming), 95972 (Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, up to one hour) and 95973 (Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)) were reviewed and valued in the CY 2015 final rule with comment period (79 FR 67670). Due to significant time changes in the base codes, we believe the entire family detailed in Table 7 should be considered as potentially misvalued and reviewed in a manner consistent with our review of CPT codes 95971, 95972 and 95973.

TABLE 7—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED IN THE ELECTRONIC ANALYSIS OF IMPLANTED NEUROSTIMULATOR FAMILY

HCPCS	Short descriptor
95970	Analyze neurostim no prog.
95974	Cranial neurostim complex.
95975	Cranial neurostim complex.
95978	Analyze neurostim brain/1h.
95979	Analyz neurostim brain addon.
95980	Io anal gast n-stim init.
95981	Io anal gast n-stim subsq.
95982	Io ga n-stim subsq w/reprog.

c. Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More

In the CY 2015 PFS rule, we proposed and finalized the high expenditure screen as a tool to identify potentially misvalued codes in the statutory category of ''codes that account for the majority of spending under the PFS.'' We also identified codes through this screen and proposed them as potentially misvalued in the CY 2015 PFS proposed rule (79 FR 40337–40338). However, given the resources required for the revaluation of codes with 10- and 90-day global periods, we did not finalize those codes as potentially misvalued codes in the CY 2015 PFS final rule with comment period. We stated that we would re-run the high expenditure screen at a future date, and subsequently propose the specific set of

codes that meet the high expenditure criteria as potentially misvalued codes (79 FR 67578).

We believe that our current resources will not necessitate further delay in proceeding with the high expenditure screen for CY 2016. We have re-run the screen with the same criteria finalized in last year's rule. However, in developing this year's proposed list, we excluded all codes with 10- and 90-day global periods since we believe these codes should be reviewed as part of the global surgery revaluation. We are proposing the 118 codes listed in Table 8 as potentially misvalued codes, identified using the high expenditure screen under the statutory category, ''codes that account for the majority of spending under the PFS.''

To develop this list, we followed the same approach taken last year except we excluded 10 and 90- day global periods. Specifically, we identified the top 20 codes by specialty (using the specialties used in Table 45) in terms of allowed charges. As we did last year, we excluded codes that we have reviewed since CY 2010, those with fewer than $10 million in allowed charges, and those that describe anesthesia or E/M services. We excluded E/M services from the list of proposed potentially misvalued codes for the same reasons that we excluded them in a similar review in CY 2012. These reasons were explained in the CY 2012 final rule with comment period (76 FR 73062 through 73065).

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPCS	Short descriptor
10022	Fna w/image
11100	Biopsy skin lesion
11101	Biopsy skin add-on
11730	Removal of nail plate
20550	Inj tendon sheath/ligament
20552	Inj trigger point 1/2 muscl
20553	Inject trigger points 3/>
22614	Spine fusion extra segment
22840	Insert spine fixation device
22842	Insert spine fixation device
22845	Insert spine fixation device
27370	Injection for knee x-ray
29580	Application of paste boot
31500	Insert emergency airway
31575	Diagnostic laryngoscopy
31579	Diagnostic laryngoscopy
31600	Incision of windpipe
33518	Cabg artery-vein two
36215	Place catheter in artery
36556	Insert non-tunnel cv cath
36569	Insert picc cath
36620	Insertion catheter artery
38221	Bone marrow biopsy
51700	Irrigation of bladder

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN—Continued

HCPCS	Short descriptor
51702	Insert temp bladder cath
51720	Treatment of bladder lesion
51728	Cystometrogram w/vp
51729	Cystometrogram w/vp&up
51784	Anal/urinary muscle study
51797	Intraabdominal pressure test
51798	Us urine capacity measure
52000	Cystoscopy
55700	Biopsy of prostate
58558	Hysteroscopy biopsy
67820	Revise eyelashes
70491	Ct soft tissue neck w/dye
70543	Mri orbt/fac/nck w/o &w/dye
70544	Mr angiography head w/o dye
70549	Mr angiograph neck w/o&w/dye
71010	Chest x-ray 1 view frontal
71020	Chest x-ray 2vw frontal&latl
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
72195	Mri pelvis w/o dye
72197	Mri pelvis w/o & w/dye
73110	X-ray exam of wrist
73130	X-ray exam of hand
73718	Mri lower extremity w/o dye
73720	Mri lwr extremity w/o&w/dye
74000	X-ray exam of abdomen
74022	X-ray exam series abdomen
74181	Mri abdomen w/o dye
74183	Mri abdomen w/o & w/dye
75635	Ct angio abdominal arteries
75710	Artery x-rays arm/leg
75978	Repair venous blockage
76512	Ophth us b w/non-quant a
76519	Echo exam of eye
76536	Us exam of head and neck
77059	Mri both breasts
77263	Radiation therapy planning
77334	Radiation treatment aid(s)
77470	Special radiation treatment
78306	Bone imaging whole body
78452	Ht muscle image spect mult
88185	Flowcytometry/tc add-on
88189	Flowcytometry/read 16 & >
88321	Microslide consultation
88360	Tumor immunohistochem/manual
88361	Tumor immunohistochem/comput
91110	Gi tract capsule endoscopy
92002	Eye exam new patient
92136	Ophthalmic biometry
92240	Icg angiography
92250	Eye exam with photos
92275	Electroretinography
92557	Comprehensive hearing test
92567	Tympanometry
93280	Pm device progr eval dual
93288	Pm device eval in person
93293	Pm phone r-strip device eval
93294	Pm device interrogate remote
93295	Dev interrog remote 1/2/mlt
93296	Pm/icd remote tech serv
93306	Tte w/doppler complete
93350	Stress tte only
93351	Stress tte complete
93503	Insert/place heart catheter
93613	Electrophys map 3d add-on
93965	Extremity study
94010	Breathing capacity test
94620	Pulmonary stress test/simple

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN—Continued

HCPCS	Short descriptor
95004	Percut allergy skin tests
95165	Antigen therapy services
95957	Eeg digital analysis
96101	Psycho testing by psych/phys
96116	Neurobehavioral status exam
96118	Neuropsych tst by psych/phys
96360	Hydration iv infusion init
96372	Ther/proph/diag inj sc/im
96374	Ther/proph/diag inj iv push
96375	Tx/pro/dx inj new drug addon
96401	Chemo anti-neopl sq/im
96402	Chemo hormon antineopl sq/im
96409	Chemo iv push sngl drug
96411	Chemo iv push addl drug
96567	Photodynamic tx skin
96910	Photochemotherapy with uv-b
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

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

The CPT manual includes more than 400 diagnostic and therapeutic procedures, listed in Appendix G, for which CPT has determined that moderate sedation is an inherent part of furnishing the procedure. Therefore, only the procedure code is reported when furnishing the service, and in developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation of these diagnostic and therapeutic procedures. To the extent that moderate sedation is inherent in the diagnostic or therapeutic service, we believe that the inclusion of moderate sedation in the valuation of the procedure is accurate. 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. Due to the changing nature of medical practice, we noted that we were considering establishing a uniform approach to valuation for all Appendix G services. We continue to seek an approach that is based on using the best available objective information about the provision of moderate sedation broadly, rather than merely addressing this issue on a code-by-code basis using RUC survey data when individual procedures

are revalued. We sought public comment on approaches to address the appropriate valuation of these services given that moderate sedation is no longer inherent for many of these services. To the extent that Appendix G procedure values are adjusted to no longer include moderate sedation, we requested suggestions as to how moderate sedation should be reported and valued, and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

To establish an approach to valuation for all Appendix G services based on the best data about the provision of moderate sedation, we need to determine the extent of the misvaluation for each code. We know that there are standard packages for the direct PE inputs associated with moderate sedation, and we began to develop approaches to estimate how much of the work is attributable to moderate sedation. However, we believe that we should seek input from the medical community prior to proposing changes in values for these services, given the different methodologies used to develop work RVUs for the hundreds of services in Appendix G. Therefore, we are seeking recommendations from the RUC and other interested stakeholders for appropriate valuation of the work associated with moderate sedation before formally proposing an approach that allows Medicare to adjust payments based on the resource costs associated with the moderate sedation or anesthesia services that are being furnished.

The anesthesia procedure codes 00740 (Anesthesia for procedure on gastrointestinal tract using an endoscope) and 00810 (Anesthesia for procedure on lower intestine using an endoscope) are used for anesthesia furnished in conjunction with lower GI procedures. In reviewing Medicare claims data, we noted that a separate anesthesia service is now reported more than 50 percent of the time that several types of colonoscopy procedures are reported. 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 re-examined. Therefore, we are proposing to identify CPT codes 00740 and 00810 as potentially misvalued. We welcome comments on both of these issues.

6. Improving the Valuation and Coding of the Global Package

a. Proposed Transition of 10-Day and 90-Day Global Packages Into 0-Day Global Packages

In the CY 2015 PFS final rule (79 FR 67582 through 67591) we finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre- and post-operative visits and performance of the surgical procedure. Although we have marginally addressed some of the concerns noted with global packages in previous rulemaking, we believe there is still an unmet need to address some of the fundamental issues with the 10- and 90-day post-operative global packages. We believe it is critical that the RVUs used to develop PFS payment rates reflect the most accurate resource costs associated with PFS services. We believe that valuing global codes that package services together without objective, auditable data on the resource costs associated with the components of the services contained in the packages may significantly skew relativity and create unwarranted payment disparities within PFS fee-for-service payment. We also believe that the resource based valuation of individual physicians' services will continue to serve as a critical foundation for Medicare payment to physicians. Therefore, we believe it is critical 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.

We stated our belief that transforming all 10- and 90-day global codes to 0-day global codes would:

- Increase the accuracy of PFS payment by setting payment rates for individual services based more closely upon 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; and
- Facilitate availability of more accurate data for new payment models and quality research.

b. Impact of the Medicare Access and CHIP Reauthorization Act of 2015

The Medicare Access and CHIP Reauthorization Act (MACRA) was enacted into law on April 16, 2015. Section 523 of the MACRA addresses payment for global surgical packages. Section 523(a) adds a new paragraph at section 1848(c)(8) of the Act. Section 1848(c)(8)(A)(i) of the Act prohibits the Secretary from implementing the policy established in the CY 2015 PFS final rule with comment period that would have transitioned all 10-day and 90-day global surgery packages to 0-day global periods. Section 1848(c)(8)(A)(ii) of the Act provides that nothing in the previous clause shall be construed to prevent the Secretary from revaluing misvalued codes for specific surgical services or assigning values to new or revised codes for surgical services.

Section 1848(c)(8)(B)(i) of the Act requires CMS 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 shall 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, 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 must reassess the value of this collected information, and allows us to discontinue the collection if the Secretary determines that we have adequate information from other sources in order to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General will audit a sample of the collected information to verify its accuracy. Section 1848(c)(8)(C) of the Act 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. Section 523(b) of the MACRA adds a new paragraph at section 1848(c)(9) of the Act which 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.

Since section 1848(c)(8)(B)(i) of the Act, as added by section 523(a) of the MACRA, requires us to use rulemaking

to develop and implement the process to gather information needed to value surgical services no later than January 1, 2017, we are seeking input from stakeholders on various aspects of this task. We are soliciting comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services. We are also seeking comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we seek 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 will use the information from the public comments to help develop a proposed approach for the collection of this information in future rulemaking.

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 previous rulemaking (79 FR 67582 through 67591) the limitations and difficulties involved in the appropriate valuation of the global packages, especially when the values of the component services are not clear. We are seeking public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and post-operative care, including the follow-up care during post-operative days. We are particularly interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, we seek information from stakeholders on whether (both qualitatively and quantitatively) postoperative visits differ from other E/M services. We are also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during post-operative care. We believe that stakeholder input regarding these questions will help determine what data should be collected, as well as how to improve the accuracy of the valuations. We welcome the full range of public feedback from stakeholders to assist us in this process.

We intend to provide further opportunities for public feedback prior to developing a proposal for CY 2017 to collect this required data. We also seek comments regarding stakeholder interest in the potential for an open door forum, town hall meetings with the public, or other avenues for direct communication regarding implementation of these provisions of the Act.

D. Refinement Panel

1. Background

As discussed in the CY 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be composed of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services.

Following enactment of section 1848(c)(2)(K) of the Act, which required the Secretary periodically to identify and review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we continued using the established refinement panel process with some modifications.

For CY 2015, in light of the changes we made to the process for valuing new, revised and potentially misvalued codes (79 FR 67606), we reassessed the role that the refinement panel process plays in the code valuation process. We noted that the current refinement panel process is tied to the review of interim final values. It provides an opportunity for stakeholders to provide new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted in the interim final value process. For CY 2015 interim final rates, we stated in the CY 2015 PFS final rule with comment period that we will use the refinement panel process as usual for these codes (79 FR 67609).

2. CY 2016 Refinement Panel Proposal

Beginning in CY 2016, we are proposing to permanently eliminate the refinement panel and instead publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. For example, we will publish the proposed rates for all CY 2016 interim final codes in the CY 2017 PFS proposed rule. With the change in the process for valuing codes adopted in the CY 2015 final rule with comment period (79 FR 67606), proposed values for most codes that are being valued for CY 2016 will be published in the CY 2016 PFS proposed rule. As explained in the CY 2015 final rule with comment period, only a small number of codes being valued for CY 2016 will be published as interim final in the 2016 PFS final rule with comment period and be subject to comment. We will evaluate the comments we receive on these code values, and both respond to these comments and propose values for these codes for CY 2017 in the CY 2017 PFS proposed rule. Therefore, stakeholders will have two opportunities to comment and to provide any new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted on an interim final basis. We believe that this proposed process, which includes two opportunities for public notice and comment, offers stakeholders a better mechanism and ample opportunity for providing any additional data for our consideration, and discussing any concerns with our interim final values, than the current refinement process. It also provides greater transparency because comments on our rules are made available to the public at *www.regulations.gov*. We welcome comments on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

E. Improving Payment Accuracy for Primary Care and Care Management Services

We are committed to supporting primary care, and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve the accuracy of payment for, and encourage long-term investment in, care management services.

In addition to the Medicare Shared Savings Program, various demonstration initiatives including the Pioneer Accountable Care Organization (ACO), the patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP), the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration, the Comprehensive Primary Care (CPC) initiative, among others (see the CY 2015 PFS final rule (79 FR 67715) for a discussion of these), we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. The payment for some non-face-to-face care management services is bundled into the payment for face-to-face evaluation and management (E/M) visits. However, because the current E/M office/outpatient visit CPT codes were designed with an overall orientation toward episodic treatment, we have recognized that these E/M codes may not reflect all the services and resources involved with furnishing certain kinds of care, particularly comprehensive, coordinated care management for certain categories of beneficiaries.

Over several years, we have developed proposals and sought stakeholder input regarding potential PFS refinements to improve the accuracy of payment for care management services. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for transitional care management (TCM) involving the transition of a beneficiary from care furnished by a treating physician during an inpatient stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993). In the CY 2014 PFS final rule with comment period, we finalized a policy, beginning in CY 2015 (78 FR 74414), to pay separately for chronic care management (CCM) services furnished to Medicare beneficiaries with two or more chronic conditions. We believe that these new separately billable codes more accurately describe, recognize, and make payment for non-face-to-face care management services furnished by practitioners and clinical staff to particular patient populations.

We view ongoing refinements to payment for care management services as part of a broader strategy to incorporate input and information gathered from research, initiatives, and demonstrations conducted by CMS and other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and, more generally, from the public at large. Based on input and information gathered from these sources, we are considering several potential refinements that would continue our efforts to improve the accuracy of PFS payments. In this section, we discuss these potential refinements.

1. Improved Payment for the Professional Work of Care Management Services

Although both the TCM and CCM services describe certain aspects of professional work, some stakeholders have suggested that neither of these new sets of codes nor the inputs used in their valuations explicitly account for all of the services and resources associated with the more extensive cognitive work that primary care physicians and other practitioners perform in planning and thinking critically about the individual chronic care needs of particular subsets of Medicare beneficiaries. Stakeholders assert that the time and intensity of the cognitive efforts are in addition to the work typically required to supervise and manage the clinical staff associated with the current TCM and CCM codes. Similarly, we continue to receive requests from a few stakeholders for CMS to lead efforts to revise the current CPT E/M codes or construct a new set of E/M codes. The goal of such efforts would be to better describe and value the physician work (time and intensity) specific to primary care and other cognitive specialties in the context of complex care of patients relative to the time and intensity of the procedure-oriented care physicians and practitioners, who use the same codes to report E/M services. Some of these stakeholders have suggested that in current medical practice, many physicians, in addition to the time spent treating acute illnesses, spend substantial time working toward optimal outcomes for patients with chronic conditions and patients they treat episodically, which can involve additional work not reflected in the codes that describe E/M services since that work is not typical across the wide range of practitioners that report the same codes. According to these groups, this work involves medication reconciliation, the assessment and integration of numerous data points, effective coordination of care among multiple other clinicians, collaboration with team members, continuous development and modification of care plans, patient or caregiver education, and the communication of test results.

We agree with stakeholders that it is important for Medicare to use codes that accurately describe the services furnished to Medicare beneficiaries and to accurately reflect the relative resources involved with furnishing those services. Therefore, we are interested in receiving public comments on ways to recognize the different resources (particularly in cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the codes that describe the broader range of E/M services. The resource costs of this work may include the time and intensity related to the management of both long-term and, in some cases, episodic conditions. In order to appropriately recognize the different resource costs for this additional cognitive work within the structure of PFS resource-based payments, we are particularly interested in codes that could be used in addition to, not instead of, the current E/M codes.

In principle, these codes could be similar to the hundreds of existing add-on codes that describe additional resource costs, such as additional blocks or slides in pathology services, additional units of repair in dermatologic procedures, or additional complexity in psychotherapy services. For example, these codes might allow for the reporting of the additional time and intensity of the cognitive work often undertaken by primary care and other cognitive specialties in conjunction with an evaluation and management service, much like add-on codes for certain procedures or diagnostic test describe the additional resources sometimes involved in furnishing those services. Similar to the CCM code, the codes might describe the increased resources used over a longer period of time than during one patient visit. For example, the add-on codes could describe the professional time in excess of 30 minutes and/or a certain set of furnished services, per one calendar month for a single patient to coordinate care, provide patient or caregiver education, reconcile and manage medications, assess and integrate data, or develop and modify care plans. Such activity may be particularly relevant for the care of patients with multiple or complicated chronic or acute conditions and should contribute to optimal patient outcomes, including more coordinated, safer care.

Like CCM, we would require that the patient have an established relationship with the billing professional; and additionally, the use of an add-on code would require the extended professional resources to be reported with another

separately payable service. However, in contrast to the CCM code, the new codes might be reported based on the resources involved in professional work, instead of the resource costs in terms of clinical staff time. The codes might also apply broadly to patients in a number of different circumstances, and would not necessarily make reporting the code(s) contingent on particular business models or technologies for medical practices. We are interested in stakeholder comments on the kinds of services that involve the type of cognitive work described above and whether or not the creation of particular codes might improve the accuracy of the relative values used for such services on the PFS. Finally, we are interested in receiving information from stakeholders on the overlap between the kinds of cognitive resource costs discussed above and those already accounted for through the currently payable codes that describe CCM and other care management services.

We strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipate using this approach, which would parallel our multi-year approach for implementing CCM and TCM services, in order to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

2. Establishing Separate Payment for Collaborative Care

We believe that the care and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information-sharing and planning between a primary care physician and a specialist (for example, with a neurologist for a patient with Alzheimer's disease plus other chronic diseases). We note that for CY 2014, CPT created four codes that describe interprofessional telephone/internet consultative services (CPT codes 99446–99449). Because Medicare pays for telephone consultations with or about a beneficiary as a part of other services furnished to the beneficiary, we currently do not make separate payment for these services. We note that such interprofessional consultative services are distinct from the face-to-face visits previously reported to Medicare using the consultation codes, and we refer the reader to the CY 2010 PFS final rule for information regarding Medicare payment policies for those services (74 FR 61767).

However, in considering how to improve the accuracy of our payments for care coordination particularly for patients requiring more extensive care, we are seeking comment on how Medicare might accurately account for the resource costs of a more robust interprofessional consultation within the current structure of PFS payment. For example, we would be interested in stakeholders' perspectives regarding whether there are conditions under which it might be appropriate to make separate payment for services like those described by these CPT codes. We are interested in stakeholder input regarding the parameters of, and resources involved in these collaborations between a specialist and primary care practitioner, especially in the context of the structure and valuation of current E/M services. In particular, we are interested in comments about how these collaborations could be distinguished from the kind of services included in other E/M services, how these services could be described if stakeholders believe the current CPT codes are not adequate, and how these services should be valued on the PFS. We are also interested in comments on whether we should tie those interprofessional consultations to a beneficiary encounter and on developing appropriate beneficiary protections to ensure that beneficiaries are fully aware of the involvement of the specialist in the beneficiary's care and the associated benefits of the collaboration between the primary care physician and the specialist physician prior to being billed for such services.

Additionally, we are seeking comment on whether this kind of care might benefit from inclusion in a CMMI model that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variation of payment amounts for the consulting and the primary care practitioners. Without such protections, beneficiaries could be responsible for coinsurance for services of physicians whose role in the beneficiary's care is not necessarily understood by the beneficiary. Finally, we also are seeking comment on key technology supports needed to support collaboration between specialist and primary care practitioners in support of high quality care management services, on whether we should consider including technology requirements as part of any proposed services, and on how such requirements could be implemented in a way that minimizes burden on providers. We strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipate using this approach, which would parallel our multi-year approach for implementing CCM and TCM services, in order to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

a. Collaborative Care Models for Beneficiaries With Common Behavioral Health Conditions

In recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with common behavioral health conditions called ''Collaborative Care.'' Collaborative care 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. Several resources have been published that describe collaborative care models in greater detail and assess their impact, including pieces from the University of Washington (*http://aims.uw.edu/*), the Institute for Clinical and Economic Review (*http://ctaf.org/reports/integration-behavioral-health-primary-care*), and the Cochrane Collaboration (*http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-for-people-with-depression-and-anxiety*).

Because this particular kind of collaborative care model has been tested and documented in medical literature, we are particularly interested in seeking comment on how coding under the PFS might facilitate appropriate valuation of the services furnished under such a collaborative care model. As these kinds of collaborative models of care become more prevalent, we will evaluate potential refinements to the PFS to account for the provision of services through such a model. We are seeking information to assist us in considering refinements to coding and payment to

address this model in particular. We also would assess application of the collaborative care model for other diagnoses and treatment modalities. For example, we seek comments on how a code similar to the CCM code applicable to multiple diagnoses and treatment plans could be used to describe collaborative care services, as well as other interprofessional services and could be appropriately valued and reported within the resource-based relative value PFS system, and how the resources involved in furnishing such services could be incorporated into the current set of PFS codes without overlap. We also request input on whether requirements similar to those used for CCM services should apply to a new collaborative care code, and whether such a code could be reported in conjunction with CCM or other E/M services. For example, we might consider whether the code should describe a minimum amount of time spent by the psychiatric consultant for a particular patient per one calendar month and be complemented by either the CCM or other care management code to support the care management and primary care elements of the collaborative care model. As with our discussion on interprofessional consultation in this section of the proposed rule, because the patient may not have direct contact with the psychiatric consultant, we seek comment on whether and, if so, how written consent for the non-face-to-face services should be required prior to practitioners reporting any new interprofessional consultation code or the care management code.

We are also seeking comment on appropriate care delivery requirements for billing, the appropriateness of CCM technology requirements or other technology requirements for these services, necessary qualifications for psychiatric consultants, and whether or not there are particular conditions for which payment would be more appropriate than others; as well as how these services may interact with quality reporting, the resource inputs we might use to value the services under the PFS (specifically, work RVUs, time, and direct PE inputs), and whether or not separate codes should be developed for the psychiatric consultant and the care management components of the service.

We are also seeking comment on whether this kind of care model should be implemented through a CMMI demonstration that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variation of payment methodology and amounts for the psychiatric consultant and the primary care physician. Again, we strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017.

3. CCM and TCM Services

a. Reducing Administrative Burden for CCM and TCM Services

In CY 2013, we implemented separate payment for TCM services, and in CY 2015, we implemented separate payment for CCM services. Both have many service elements and billing requirements that the physician or nonphysician practitioner must satisfy in order to fully furnish these services and to report these codes (77 FR 68989, 79 FR 67728). These elements and requirements are relatively extensive and generally exceed those for other E/M and similar services. Since the implementation of these services, some practitioners have stated that the service elements and billing requirements are too burdensome, and suggested that they interfere with their ability to provide these care management services to their patients who could benefit from them. In light of this feedback from the physician and practitioner community, we are soliciting comments on steps that we could take to further improve beneficiary access to TCM and CCM services. Our aims in implementing separate payment for these services are that Medicare practitioners are paid appropriately for the services they furnish, and that beneficiaries receive comprehensive care management that benefits their long term health outcomes. However, we understand that excessive requirements on practitioners could possibly undermine the overall goals of the payment policies. We are interested in stakeholder input in how we can best balance access to these services and practitioner burdens such that Medicare beneficiaries may obtain the full benefit of these services.

b. Payment for CPT Codes Related to CCM Services

As we stated in the CY 2015 PFS final rule (79 FR 67719), we believe that Medicare beneficiaries with two or more chronic conditions as defined under the CCM code can benefit from the care management services described by that code, and we want to make this service available to all such beneficiaries. As with most services paid under the PFS, we recognize that furnishing CCM services to some beneficiaries will require more resources and some less; but we value and make payment based upon the typical service. Because CY 2015 is the first year for which we are making separate payment for CCM services, we are seeking information regarding the circumstances under which this service is furnished. This information includes the clinical status of the beneficiaries receiving the service and the resources involved in furnishing the service, such as the number of documented non-face-to-face minutes furnished by clinical staff in the months the code is reported. We would be interested in examining such information in order to identify the range of minutes furnished over those months as well as the distribution of the number of minutes within the total volume of services. We are also seeking objective data regarding the resource costs associated with furnishing the services described by this code. As we review that information, in addition to our own claims data, we will consider any changes in payment and coding that may be warranted in the coming years, including the possibility of establishing separate payment amounts and making Medicare payment for the related CPT codes, such as the complex care coordination codes, CPT codes 99487 and 99489.

F. Target for Relative Value Adjustments for Misvalued Services

Section 220(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added a new subparagraph at 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. Under section 1848(c)(2)(O)(ii) of the Act, if the estimated net reduction in expenditures for a 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. 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 amount by which the target for the year exceeds 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. Section 220(d) of the PAMA applied to calendar years (CYs) 2017 through 2020 and set the target under section 1848(c)(2)(O)(v) of the Act at 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years.

Section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014)) amended section 1848(c)(2)(O) of the Act to accelerate the application of the PFS expenditure reduction target to CYs 2016, 2017, and 2018, and to set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. As a result of these provisions, if the estimated net reduction for a given year is less than the target for that year, payments under the fee schedule will be reduced.

In this section, we are proposing a methodology to implement this statutory provision in a manner consistent with the broader statutory construct of the PFS. In developing this proposed methodology, we have identified several aspects of our approach for which we are specifically seeking comment. We have organized this discussion by identifying and explaining these aspects in particular but we are seeking comment on all aspects of our proposal.

1. Distinguishing ''Misvalued Code'' Adjustments From Other RVU Adjustments

The potentially misvalued code initiative has resulted in changes in PFS payments in several ways. First, potentially misvalued codes have been identified, reviewed, and revalued through notice and comment rulemaking. However, in many cases, the identification of particular codes as potentially misvalued has led to the review and revaluation of related codes, and frequently, to revisions to the underlying coding for large sets of related services. Similarly, the review of individual codes has initiated reviews and proposals to make broader adjustments to values for codes across the PFS, such as when the review of a series of imaging codes prompted a RUC recommendation and CMS proposal to update the direct PE inputs for imaging services to assume digital instead of film costs. This change, originating through the misvalued code initiative, resulted in a significant reduction in RVUs for a large set of PFS services, even though the majority of affected codes were not initially identified through potentially misvalued code screens. Finally, due to both the relativity inherent in the PFS ratesetting process and the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, adjustments to the RVUs for individual services necessarily result in the shifting of RVUs to broad sets of other services across the PFS.

To implement the PFS expenditure reduction target provisions under section 1848(c)(2)(O) of the Act, we must identify a subset of the adjustments in RVUs for a year to reflect an estimated ''net reduction'' in expenditures. Therefore, we dismissed the possibility of including all changes in RVUs for a year in calculating the estimated net reduction in PFS expenditures, even though we believe that the redistributions in RVUs to other services are an important aspect of the potentially misvalued code initiative. Conversely, we similarly considered the possibility of limiting the calculation of the estimated net reduction in expenditures to reflect RVU adjustments made to the codes formally identified as ''potentially misvalued.'' We do not believe that calculation would reflect the significant changes in payments that have directly resulted from the review and revaluation of misvalued codes under section 1848(c)(2) of the Act. We further considered whether to include only those codes that underwent a comprehensive review (work and PE). As we previously have stated (76 FR 73057), we believe that a comprehensive review of the work and PE for each code leads to the more accurate assignment of RVUs and appropriate payments under the PFS than do fragmentary adjustments for only one component. However, if we calculated the net reduction in expenditures using revisions to RVUs only from comprehensive reviews, the calculation would not include changes in PE RVUs that result from proposals like the film-to-digital change for imaging services, which not only originated from the review of potentially misvalued codes, but substantially improved the accuracy of PFS payments faster and more efficiently than could have been done through the multiple-year process required to complete a comprehensive review of all imaging codes.

After considering these options, we believe that the best approach is to define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values. This would limit the pool of RVU adjustments used to calculate the net reduction in expenditures to those for the services for which individual, comprehensive review or broader proposed adjustments have resulted in changes to service-level inputs of work RVUs, direct PE inputs, or MP RVUs, as well as services directly affected by changes to coding for related services. For example, coding changes in certain codes can sometimes necessitate revaluations for related codes that have not been reviewed as misvalued codes, because the coding changes have also affected the scope of the related services. This definition would incorporate all reduced expenditures from revaluations for services that are deliberately addressed as potentially misvalued codes, as well as those for services with broad-based adjustments like film-to-digital and services that are redefined through coding changes as a result of the review of misvalued codes.

Because the annual target is calculated by measuring changes from one year to the next, we also considered how to account for changes in values that are best measured over 3 years, instead of 2 years. Under our current process, the overall change in valuation for many misvalued codes is measured across values for 3 years: The original value in the first year, the interim final value in the second year, and the finalized value in the third year. As we describe in section II.I.2. of this proposed rule, our misvalued code process has been to establish interim final RVUs for the potentially misvalued, new, and revised codes 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 accept public comment about those valuations. For the final rule with comment period for the subsequent year, we consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. However, the straightforward calculation of the target would only compare changes 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. 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 is particularly problematic for calculating the target for CY 2016 for two reasons. First, CY 2015 was the final full year of establishing interim final values for all new, revised, and potentially misvalued codes. Starting with this proposed rule, we are proposing and finalizing values for a significant portion of misvalued codes during one calendar year. Therefore, CY 2015 will include a disproportionate number of services that would be measured between years 2 and 3 relative to the services measured between 1 and 2 years. Second, 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 were to include 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 are proposing 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.

We note that the impact of interim final values in the calculation of targets for future years will be diminished as we transition to proposing values for almost all new, revised, and potentially misvalued codes in the proposed rule. We anticipate a smaller number of interim final values for CY 2016 relative to CY 2015. For calculation of the CY 2018 target, we anticipate almost no impact based on misvalued code adjustments that occur over multiple years.

The list of codes with proposed changes for CY 2016 included under this proposed definition of ''adjustments to RVUs for misvalued codes'' is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

2. Calculating ''Net Reduction''

Once the RVU changes attributable to misvalued codes are identified, estimated net reductions would be calculated summing the decreases and offsetting any applicable increases in valuation within the changes defined as misvalued, as described above. Because the provision only explicitly addresses reductions, and we recognize many stakeholders will want to maximize the overall magnitude of the measured reductions in order to prevent an overall reduction to the PFS conversion factor, we considered the possibility of ignoring the applicable increases in valuation in the calculation of net reduction. However, we believe that the requirement to calculate ''net'' reductions implies that we are to take into consideration both decreases and increases. Additionally, we believe this approach may be the only practical one due to the presence of new and deleted codes on an annual basis.

For example, a service that is described by a single code in a given year, like intensity-modulated radiation therapy (IMRT) treatment delivery, could be addressed as a misvalued service in a subsequent year through a coding revision that splits the service into two codes, ''simple'' and ''complex.'' If we counted only the reductions in RVUs, we would count only the change in value between the single code and the new code that describes the ''simple'' treatment delivery code. In this scenario, the change in value from the single code to the new ''complex'' treatment delivery code would be ignored, so that even if there were an increase in the payment for IMRT treatment delivery service(s) overall, the mere change in coding would contribute inappropriately to a ''net reduction in expenditures.'' Therefore, we are proposing to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes.

3. Measuring the Adjustments

The most straightforward method to estimating the net reduction in expenditures due to adjustments to RVUs for misvalued codes is to compare the total RVUs of the relevant set of codes (by volume) in the current year to the update year, and divide that by the total RVUs for all codes (by volume) for the current year. This approach is intuitive and relatively easy to replicate.

However, this method is imprecise for several reasons. First, and most significantly, the code-level PE RVUs in the update year include either increases due to the redistribution of RVUs from other services or reductions due to increases in PE for other services. Second, because relativity for work RVUs is maintained through annual adjustments to the CF, the precise value of a work RVU in any given year is adjusted based on the total number of work RVUs in that year. Finally, relativity for the MP RVUs is maintained by both redistribution of MP RVUs and adjustments to the CF, when necessary (under our proposed methodology this is true annually; based on our established methodology the redistribution of the MP RVUs only takes place once every 5 years and the CF is adjusted otherwise). Therefore, to make a more precise assessment of the net reduction in expenditures that are the result of adjustments to the RVUs for misvalued codes, we would need to compare, for the included codes, the update year's total work RVUs (by volume), direct PE RVUs (by volume), indirect PE RVUs (by volume), and MP RVUs (by volume) to the same RVUs in the current year, prior to the application of any scaling factors or adjustments. This would make for a direct comparison between years.

However, this approach would mean that the calculation of the net reduction in expenditures would occur within various steps of the PFS ratesetting methodology. While we believe that this approach would be transparent and external stakeholders could replicate this method, it may be difficult and time-consuming for stakeholders to do so. We also noted that when we modeled the interaction of the phase-in legislation and the calculation of the target using this approach during the development of this proposal, there were methodological challenges in making these calculations. When we simulated the two approaches using

information from prior PFS years, we found that both approaches generally resulted in similar estimated net reductions. After considering these options, we are proposing to use the approach of comparing the total RVUs (by volume) for the relevant set of codes in the current year to the update year, and divide that result by the total RVUs (by volume) for the current year. We seek comment on whether comparing the update year's work RVUs, direct PE RVUs, indirect PE RVUs, and MP RVUs for the relevant set of codes (by volume) prior to the application of any scaling factors or adjustments to those of the current year would be a preferable methodology for determining the estimated net reduction.

4. Estimating the Target for CY 2016

CY 2016 represents a transition year in our new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period. For CY 2016, we will propose values for which we had the RUC's recommendations by our deadline of February 10th, and will establish interim final values for any codes received after the February 10th deadline but in time for us to value for the final rule. For CY 2016, there will still be a significant number of codes valued not in the proposed rule but in the final rule with comment period. In future years (with the exception of entirely new services), all codes, even those for which we do not receive RUC recommendations in time for the proposed rule, will be in the proposed rule for the subsequent year and not in the final rule with comment period. Therefore, for CY 2016, unlike for the targets for CY 2017 and CY 2018, because we will not be able to calculate a realistic estimate of the target amount at the time the proposed rule is published, we will not incorporate the impact of the target into the calculation of the proposed PFS payment rates. However, because we would apply any required budget neutrality adjustment related to this provision to the conversion factor, the proposed RVUs for individual services in this proposed rule would be the same, regardless of the estimate of the target. We also refer readers to the regulatory impact analysis section of this proposed rule for an interim estimate of the estimated net reduction in expenditures relative to the 1 percent target for CY 2016, based solely on the proposed changes in this rule.

G. Phase-in of Significant RVU Reductions

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, also 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. Although section 220(e) of the PAMA required the phase-in to begin for 2017, section 202 of the ABLE Act amended section 1848(c)(7) of the Act to require that the phase-in begin for CY 2016.

In this section, we are proposing a methodology to implement this statutory provision. In developing this proposed methodology, we have identified several aspects of our approach for which we are specifically seeking comment, given the challenges inherent in implementing this provision in a manner consistent with the broader statutory construct of the PFS. We have organized this discussion by identifying and explaining these aspects in particular but we are seeking comment on all aspects of our proposal.

1. Identifying Services that are Not New or Revised Codes

As described in this proposed rule, the statute specifies that services described by new or revised codes are not subject to the phase-in of RVUs. We believe this exclusion recognizes the reality that there is no practical way to phase-in over 2 years changes to RVUs that occur as a result of a coding change for a particular service because there is no relevant reference code or value on which to base the transition. To determine which services are described by new or revised codes for purposes of the phase-in provision, we are proposing to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year. This approach would exclude services described by new codes or existing codes for which the descriptors were altered substantially for the update year to change the services that are reported using the code. We would also exclude as new and revised codes those codes that describe a different set of services in the update year when compared to the current year by virtue of changes in other, related codes, or codes that are part of a family with significant coding revisions. For example, significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family would also help to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. This proposed application of the phase-in would also be consistent with previous RVU transitions, especially for PE RVUs, for which we only applied transition values to those codes that described the same service in both the current and the update years. We would also exclude from the phase-in as new and revised codes those codes with changes to the global period, since the code in the current year would not describe the same units of service as the code in the update year.

2. Estimating the 20 Percent Threshold

Because the phase-in of RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we are proposing to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. We recognize that the result of this approach could mean that some codes may not qualify for the phase-in despite a reduction in RVUs that is ultimately slightly greater than 20 percent due to budget neutrality adjustments that are made after identifying the codes that meet the threshold in order to reflect the phase-in values for other codes. We believe the only alternative to this approach is not practicable, since it would be circular, resulting in cyclical iteration.

3. RVUs in the First Year of the Phase-In

Section 1848(c)(7) of the Act states 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 is estimated to be equal to or greater than 20 percent. We believe that there are two reasonable ways to determine the portion of the reduction to be phase-in for the first year. Most recent RVU transitions have distributed the values evenly across several years. For example, for a 2-year transition we would estimate the fully implemented value and set a rate

approximately 50 percent between the value for the current year and the value for the update year. We believe that this is the most intuitive approach to the phase-in and is likely the expectation for many stakeholders. However, we believe that the 50 percent phase-in in the first year has a significant drawback. For instance, since the statute establishes a 20 percent threshold as the trigger for phasing in the change in RVUs, under the 50 percent phase-in approach, a service that is estimated to be reduced by a total of 19 percent for an update year would be reduced by a full 19 percent in that update year, while a service that is estimated to be reduced by 20 percent in an update year would only be reduced 10 percent in that update year.

The logical alternative approach is to consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach would be to reduce the service by the maximum allowed amount (that is, 19 percent) in the first year, and then phase in the remainder of the reduction in the second year. Under this approach, the code that is reduced by 19 percent in a year and the code that would otherwise have been reduced by 20 percent would both be reduced by 19 percent in the first year, and the latter code would see an additional 1 percent reduction in the second year of the phase-in. For most services, this would likely mean that the majority of the reduction would take place in the first year of the phase-in. However, for services with the most drastic reductions (greater than 40 percent), the majority of the reduction would take place in the second year of the phase-in.

After considering both of these options, we are proposing to consider the 19 percent reduction as the maximum 1-year reduction and to phase-in any remaining reduction greater than 19 percent in the second year of the phase-in. We believe that this approach is more equitable for codes with significant reductions but that are less than 20 percent. We are seeking comment on this proposal.

4. Applicable Adjustments to RVUs

The phase-in provision instructs that the applicable adjustments in work, PE, and MP RVUs be phased-in over 2 years for any service that would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total RVUs for the previous year. However, for several thousand services, we develop separate RVUs for facility and nonfacility sites of service. For nearly one thousand other services, we develop separate RVUs for the professional and technical components of the service and sum those RVUs to allow for global billing. Therefore, for individual practitioners furnishing particular services to Medicare beneficiaries, the relevant changes in RVUs for a particular code are based on the total RVUs for a code for a particular setting (facility/nonfacility) or for a particular component (professional/technical). We believe the most straightforward and fair approach to addressing both the site of service differential and the codes with professional and technical components is to consider the RVUs for the different sites of service and components independently for purposes of identifying when and how the phase-in applies. We are proposing, therefore, to estimate whether a particular code meets the 20 percent threshold for change in total RVUs by taking into account the total RVUs that apply to a particular setting or to a particular component. This would mean that if the change in total facility RVUs for a code met the threshold, then that change would be phased-in over 2 years, even if the change for the total nonfacility RVUs for the same code would not be phased-in over 2 years. Similarly, if the change in the total RVUs for the technical component of a service meets the 20 percent threshold, then that change would be phased-in over 2 years, even if the change for the professional component did not meet the threshold. (Because the global is the sum of the professional and technical components, the portion of the global attributable to the technical component would then be phased-in, while the portion attributable to the professional component would not be.)

However, we note that we create the site of service differential exclusively by developing independent PE RVUs for each service in the nonfacility and facility settings. That is, for these codes, we use the same work RVUs and MP RVUs in both settings and vary only the PE RVUs to implement the difference in resources depending on the setting. Similarly, we use the work RVUs assigned to the professional component codes as the work RVUs for the service when billed globally. Like the codes with the site of service differential, the PE RVUs for each component are developed independently. The resulting PE RVUs are then summed for use as the PE RVUs for the code, billed globally. Since variation of PE RVUs is the only constant across all individual codes, codes with site of service differentials, and codes with professional and technical components, we are proposing to apply all adjustments for the phase-in to the PE RVUs.

We considered alternatives to this approach. For example, for codes with a site of service differential, we considered applying a phase-in for codes in both settings (and all components) whenever the total RVUs in either setting reached the 20 percent threshold. However, there are cases where the total RVUs for a code in one setting (or one component) may reach the 20 percent reduction threshold, while the total RVUs for the other setting (or other component) are increasing. In those cases, applying phase-in values for work or MP RVUs would mean applying an additional increase in total RVUs for particular services. We also considered basing the phase-in of the RVUs for the component codes billed globally and for the codes with site of service differentials developing an overall, blended set of overall PE RVUs using a weighted average of site of service volume in the Medicare claims data. We would then compare the global or blended value in the prior year versus the global or blended value in the current year and apply the phase-in to the value for the current year before re-allocating the new value to the respective RVUs in each setting. We did not pursue this approach for several reasons. First, the resulting phase-in amounts would not relate logically to the values paid to any individual practitioner, except those who bill the PC/TC codes globally. Second, the approach would be so administratively complicated that it would likely be difficult to replicate or predict.

Therefore, we have concluded that applying the adjustments to the PE RVUs for individual codes in order to effect the appropriate phase-in amount is the most straightforward and fair approach to mitigate the impact of significant reductions of total RVUs for services furnished by individual practitioners. The list of codes subject to the phase-in, and the RVUs that result from this proposed methodology, is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

H. Changes for Computed Tomography (CT) Under the Protecting Access to Medicare Act of 2014 (PAMA) (CY 2016 only)

1. Section 218(a) of the Protecting Access to Medicare Act of 2014 (PAMA)

Section 218(a) of PAMA is entitled ''Quality Incentives To Promote Patient Safety and Public Health in Computed Tomography Diagnostic Imaging.'' It amends the statute by reducing payment for the technical component (TC) (and the TC of the global fee) of the PFS service and the hospital outpatient prospective payment system (OPPS) payment (5 percent in 2016 and 15 percent in 2017 and subsequent years) for computed tomography (CT) services identified by CPT codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.''

The statutory provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard, and that such information may be included on a claim and may be a modifier. The statutory provision also provides that such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) of the Act and hospitals under section 1865(a) of the Act. Any reduced expenditures resulting from this provision are not budget neutral. To implement this provision, we will create modifier ''CT'' (Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR–29–2013 standard). Beginning in 2016, claims for CT scans described by above-listed CPT codes (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans must include modifier ''CT'' and that modifier will result in the applicable payment reduction for the service.

I. Valuation of Specific Codes

1. Background

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 assure 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 five-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 five-year review process, revisions in RVUs were proposed in a proposed rule and finalized in a final rule. In addition to the five-year reviews, in each year beginning with CY 2009, CMS and the RUC have identified a number of potentially misvalued codes using various identification screens, as discussed in section II.C. of this proposed rule. Each year, when we received RUC recommendations, our process has 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 accept public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we pay 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 consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. We then typically finalize the values for the codes.

2. Process for Valuing New, Revised, and Potentially Misvalued Codes

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. CY 2016 represents a transition year for this new process. For CY 2016, we are proposing new values in the proposed rule for the codes for which we received complete RUC recommendations by February 10, 2015. For recommendations regarding any new or revised codes received after the February 10, 2015 deadline, including updated recommendations for codes included in this proposed rule, we will establish interim final values in the final rule with comment period, consistent with previous practice. We note that we will consider all comments received in response to proposed values for codes in this rule, including alternative recommendations to those used in developing the proposed rule. In other words, if the RUC or other interested stakeholders submit public comments that include new recommendations for codes for which we propose values as part of this proposed rule, we would consider those recommendations in developing final values for the codes in the CY 2016 PFS final rule with comment.

Beginning with valuations for CY 2017, the new process will be applicable to all codes. That is, beginning with rulemaking for CY 2017, we will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary to facilitate continued payment for certain services for which we do not receive recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

For CY 2016, we received RUC recommendations prior to February 10, 2015 for many new, revised and potentially misvalued codes and have included proposed values for these codes in this proposed rule. However, the RUC recommendations included CPT tracking codes instead of the actual 2016 CPT codes that will first be made available to the public subsequent to the publication of this proposed rule. Because CPT procedure codes are 5 alpha-numeric characters but CPT tracking codes typically have 6 or 7 alpha-numeric characters and CMS systems only utilize 5-character HCPCS codes, we have developed and used alternative 5-character placeholder codes for this proposed rule. For the convenience of stakeholders and commenters with access to the CPT tracking codes, we have displayed a crosswalk from the 5-character placeholder codes to the CPT tracking codes on our Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/*. The final CPT codes will be included in the CY 2016 final rule with comment period.

3. Methodology for Establishing Work RVUs

We conducted a review of each code identified in this section and reviewed the current work RVU (if any), RUC-

recommended work RVUs, 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 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 Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule. 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 physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the PFS without explicitly valuing the components of that work.

The PFS incorporates cross-specialty and cross-organ system relativity. Valuing services requires an assessment of relative value and takes into account the clinical intensity and time required to furnish a service. 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.

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 evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. We believe 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 times 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, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

Table 11 contains a list of proposed work RVUs for all codes with RUC recommendations received by February 10, 2015. Proposed work RVUs that vary from those recommended by the RUC or for which we do not have RUC recommendations are addressed in the portions of this section that are dedicated to particular codes.

The work RVUs and other payment information for all CY 2016 payable codes are available in Addendum B, including codes for which we have proposed changes in this proposed rule subject to public comment. Addendum B is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/.* The proposed time values for all CY 2016 codes are listed in a file called ''CY 2016 PFS Work Time,'' available on the CMS Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/.*

4. Methodology for Establishing the Direct PE Inputs Used to Develop PE RVUs

a. Background

On an annual basis, the RUC provides CMS 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 Medicare 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. 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 input includes many refinements that are common

across codes as well as refinements that are specific to particular services. Table 13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this 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 impact on direct costs for that service. We point out 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 final PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU as well as the impact on the indirect allocator for the average service. We also note that nearly half of the refinements listed in Table 13 result in changes under the $0.32 threshold and are unlikely to result in a change to the final RVUs.

We also note that the proposed direct PE inputs for CY 2016 are displayed in the proposed CY 2016 direct PE input database, available on the CMS Web site under the downloads for the CY 2016 proposed rule at *www.cms.gov/PhysicianFeeSched/.* The inputs displayed there have also been used in developing the CY 2016 PE RVUs as displayed in Addendum B of this proposed rule.

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. Although the direct PE input recommendations generally correspond to the work time values associated with services, we believe that in some cases inadvertent discrepancies between work time values and direct PE inputs should be refined in the establishment of proposed direct PE inputs. In other cases, CMS refinement of recommended proposed work times prompts necessary adjustments in the direct PE inputs.

(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, 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 pre-service or post-service 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 clinical staff may be occupied with a pre-service or post-service 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. Some stakeholders have objected to this rationale for our refinement of equipment minutes on this basis. We refer readers to our extensive discussion in response to those objections 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 period, 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, CMS staff reviews 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 match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the pre-service 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. To mitigate the potential negative impact of these additions, our staff reviews 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; two examples of such tasks encountered during our review of the recommendations include ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation'' and ''Consult with pathologist regarding representation needed, block selection and appropriate technique.''

In conducting our review of the RUC recommendations for CY 2016, we noted that several of the recommended times for clinical labor tasks associated with pathology services differed across codes, both within the CY 2016 recommendations and in comparison to codes currently in the direct PE database. We refer readers to Table 6 in section II.A.3. of this proposed rule where we outline our proposed standard times for clinical labor tasks associated with pathology services.

(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 that cannot be allocated to individual services or patients. Two examples of such items are ''emergency service container/safety kit'' and ''service contract.'' We have addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use these recommended items as direct PE inputs in the calculation of PE RVUs.

(5) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043 through 73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. In the CY 2015 final rule with comment period, we finalized a refinement to the standard package to include a stretcher for the same length of time as the other equipment items in the standard package. We are proposing to refine the RUC's direct PE recommendations to conform to these policies. This includes the removal of a power table where it was included during the intraservice period, as the stretcher takes the place of the table. These refinements are reflected in the final CY 2016 PFS direct PE input database and detailed in Table 13.

(6) 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 include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide copies of sales invoices to us. We received invoices for several new supply and equipment items for CY 2016. We have accepted the majority of these items and added them to the direct PE input database. Tables 9 and 10 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this proposed rule, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database. 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 9 and 10 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. We are concerned that a single invoice may not be reflective of typical costs and 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 accept 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.

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

Several of the PE worksheets included in the RUC recommendations contained clinical labor minutes assigned to the service period in the facility setting. Our proposed inputs do not include these minutes 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.

(8) Duplicative Inputs

Several of the PE worksheets included in the RUC recommendations contained time for the equipment item ''xenon light source'' (EQ167). Because there appear 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, we are not proposing to include the time for this equipment item from these services, and are seeking comment on whether there is a rationale for including this additional light source as a direct PE input for these procedures.

5. Methodology for Establishing Malpractice RVUs

As discussed in section II.B. of this proposed rule, our malpractice methodology uses a crosswalk to establish risk factors for new services until utilization data becomes available. Table 15 lists the CY 2016 HCPCS codes and their respective source codes used to set the proposed CY 2016 MP RVUs. The MP RVUs for these services are reflected in Addendum B on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

TABLE 9—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
31626	Gold Fiducial Marker	SB053	135	1	6

TABLE 9—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
3160A, 3160B, 3160C	endoscope, ultrasound radial probe	ES045	0	0	212
3725A	IVUS catheter	SD304	1025	3	795
3725A	IVUS Catheter Sterile Cover	SD305	120	3	795
3725A, 3725B	IVUS system	ES047	134,025	3	2,948
44385, 44386, 45330, 45331, 45332, 45333, 45334, 45335, 45338, 45340, 45346.	Video Sigmoidoscope	ES043	215,00	1	18,058
44401, 45346, 45388	catheter, RF ablation, endoscopic	SC103	1,780	1	3,543
44401, 45346	radiofrequency generator, endoscopy	EQ369	108,291.67	1	174
45350, 45398	hemorrhoidal banding system	SA115	223.50	4	3
5039D, 5039M	Nephroureteral Catheter	SD306	117.90	1	70
657XG	suture, nylon, 10–0	SC104	12.17	2	
657XG	intrastromal corneal ring	SA120	1,145	7	
657XG	patient/laser interface (single—use, disposable).	SD307	172.50	1	
657XG	femtosecond laser	ES048	293,000	2	
657XG	incision programming software	ES049	10,012.50	1	
692XX	earwash bottle disposable tips	SD308	1.72	1	
77385, 77386, 77402, 77407, 77412.	Power Conditioner	ER102	26,400	2	2,198,441
7778A, 7778B, 7778C, 7778D, 7778E.	brachytherapy treatment vault	ES052	175,000	1	24,936
88104, 88106, 88108	fixative spray for cytospin	SL503	1.53	1	62,552
88108	Shannon cyto funnel, cytospin	SD298	2.27	1	48,740
88108	slide, microscope coated cytospin (single circle).	SL504	0.39	1	48,740
88182	Protease	SL506	0.43	1	568
88346, 8835X	Immunofluorescent mounting media	SD309	3.50	1	114,211
88346, 8835X	Zeus medium	SL518	0.85	2	114,211
88346, 8835X	Hydrophobic PAP Pen	SK120	1.76 (100 uses)	1	114,211
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	13.89	3	116,718

TABLE 10—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
31300, 31320, 31360, 31365, 31367, 31368, 31370, 31375, 31380, 31382, 31390, 31395, 31628, 31632, 31750, 31755, 31800, 41120, 41130, 41135, 41140, 41145, 41150, 41153, 41155, 41500, 41510, 41512, 41530, 42120, 42842, 42844, 42845, 42870, 42890, 42892, 42894, 42950, 42953, 42955, 43215, 43247, 58555, 58558, 58562, 58563, 60605, 92511, 92612.	endosheath	SD070	9.50	17.25	82	1	65,318
41530, 43228, 43229, 43270, 64633, 64634, 64635, 64636.	radiofrequency generator (NEURO).	EQ214	32,900	10,000	−70	1	265,270
88341, 88342, 88343, 88344, 88360, 88361.	Benchmark ULTRA automated slide preparation system.	EP112	134,000	150,000	12	1	3,279,993
8835X	antibody IgA FITC	SL012	71.40	41.18	−42	1	93,520
95018	benzylpenicilloyl polylysine (eg, PrePen) 0.25ml uou.	SH103	72.45	83.00	15	1	60,683

TABLE 10—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS—Continued

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
95923	kit, electrode, iontophoresis.	SA014	11.99	4.01	−67	3	96,189

6. CY 2016 Valuation of Specific Codes

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
11750	Removal of nail	2.5	1.99	1.58	No.
20240	Biopsy of bone, open procedure	3.28	3.73	2.61	No.
27280	Arthrodesis, open, sacroiliac joint including obtaining bone graft	14.64	20	20	No.
3160A	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stat.	NEW	5	4.71	No.
3160B	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stati.	NEW	5.5	5.21	No.
3160C	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to.	NEW	1.7	1.4	No.
31622	Diagnostic examination of lung airways using an endoscope	2.78	2.78	2.78	No.
31625	Biopsy of lung airways using an endoscope	3.36	3.36	3.36	No.
31626	Insertion of radiation therapy markers into lung airways using an endoscope.	4.16	4.16	4.16	No.
31628	Biopsy of one lobe of lung using an endoscope	3.8	3.8	3.8	No.
31629	Needle biopsy of windpipe cartilage, airway, and/or lung using an endoscope.	4.09	4	4	No.
31632	Biopsy of lung using an endoscope	1.03	1.03	1.03	No.
31633	Needle biopsy of lung using an endoscope	1.32	1.32	1.32	No.
3347A	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed.	NEW	25	25	No.
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection.	19.68	18	18	No.
3725A	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial non-coronary vessel (List separately in addition to code for primary procedure).	NEW	1.8	1.8	No.
3725B	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure.	NEW	1.44	1.44	No.
38570	Removal of abdominal cavity lymph nodes using an endoscope	9.34	9.34	8.49	No.
38571	Removal of total lymph nodes of both sides of pelvis using an endoscope.	14.76	12	12	No.
38572	Removal of total lymph nodes of both sides of pelvis and abdominal lymph node biopsy using an endoscope.	16.94	15.6	15.6	No.
3940A	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed.	NEW	5.44	5.44	No.
3940B	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging).	NEW	7.5	7.25	No.
43775	Stomach reduction procedure with partial removal of stomach using an endoscope.	C	21.4	20.38	No.
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.05	0.97	0.9	No.
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	N/A	1.48	1.48	Yes
44382	Ileoscopy, through stoma; with biopsy, single or multiple	1.27	1.27	1.2	No.
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	N/A	3.11	2.88	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
44385	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.82	1.3	1.23	No.
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple.	2.12	1.6	1.53	No.
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	2.82	2.82	2.75	No.
44389	Colonoscopy through stoma; with biopsy, single or multiple	3.13	3.12	3.05	No.
44390	Colonoscopy through stoma; with removal of foreign body	3.82	3.82	3.77	No.
44391	Colonoscopy through stoma; with control of bleeding, any method	4.31	4.22	4.22	No.
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.	3.81	3.63	3.63	No.
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	4.42	4.13	4.13	No.
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion (includes pre-and post-dilation and guide wire passage, when performed).	N/A	4.44	4.44	No.
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guidewire passage, when performed).	N/A	4.96	4.73	No.
44403	Colonoscopy through stoma; with endoscopic mucosal resection ...	N/A	5.81	5.53	No.
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	N/A	3.13	3.05	No.
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	N/A	3.33	3.33	No.
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	N/A	4.41	4.13	No.
44407	Colonoscopy through stoma; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjace.	N/A	5.06	5.06	No.
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	N/A	4.24	4.24	No.
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed.	0.96	0.84	0.77	No.
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	1.15	1.14	1.07	No.
45332	Sigmoidoscopy, flexible; with removal of foreign body	1.79	1.85	1.79	No.
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps.	1.79	1.65	1.65	No.
45334	Sigmoidoscopy, flexible; with control of bleeding, any method	2.73	2.1	2.1	No.
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.15	1.07	No.
45337	Sigmoidoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	2.36	2.2	2.2	No.
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	2.34	2.15	2.15	No.
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation	1.89	1.35	1.35	No.
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination ..	2.6	2.43	2.15	No.
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s).	4.05	3.08	3.08	No.
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	N/A	2.97	2.84	No.
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	N/A	2.98	2.75	No.
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	N/A	3.83	3.55	No.
45350	Sigmoidoscopy, flexible;with banding (eg, hemorrhoids)	N/A	1.78	1.78	No.
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure).	3.69	3.36	3.29	No.
45379	Colonoscopy, flexible; with removal of foreign body	4.68	4.37	4.31	No.
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.	4.43	3.66	3.59	No.
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance.	4.19	3.67	3.59	No.
45382	Colonoscopy, flexible; with control of bleeding, any method	5.68	4.76	4.76	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.	4.69	4.17	4.17	No.
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	5.3	4.67	4.67	No.
45386	Colonoscopy, flexible; with transendoscopic balloon dilation	4.57	3.87	3.87	No.
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	N/A	4.98	4.98	No.
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	N/A	5.5	5.27	No.
45390	Colonoscopy, flexible; with endoscopic mucosal resection	N/A	6.35	6.07	No.
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures.	5.09	4.95	4.67	No.
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and a.	6.54	5.6	5.6	No.
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	N/A	4.78	4.78	No.
45398	Colonoscopy, flexible; with banding, (eg, hemorrhoids)	N/A	4.3	4.3	No.
46500	Injection of hemorrhoids	1.69	1.69	1.42	No.
46601	Anoscopy; diagnostic, with high-resolution magnification	N/A	1.6	1.6	No.
46607	Anoscopy; with high-resolution magnification (hra), with biopsy, single or multiple.	N/A	2.2	2.2	No.
47135	Transplantation of donor liver to anatomic position	83.64	91.78	90	No.
50390	Aspiration and/or injection kidney cyst, accessed through the skin	1.96	1.96	1.96	No.
5039A ...	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; new access.	NEW	3.15	3.15	No.
5039B ...	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access.	NEW	1.42	1.1	No.
5039C ...	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.7	4.25	No.
5039D ...	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access.	NEW	5.75	5.3	No.
5039E ...	Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	2	1.82	No.
5039M ...	Convert nephrostomy catheter to nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.2	4	No.
5069G ...	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; pre-existing nephrostomy.	NEW	4.6	4.21	No.
5069H ...	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, without separate.	NEW	6	5.5	No.
5069I	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, with separate.	NEW	7.55	7.05	No.
5443A ...	Repair of traumatic corporeal tear(s)	NEW	11.5	11.5	No.
5443B ...	Replantation, penis, complete amputation including urethral repair	NEW	24.5	22.1	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
63045	Laminectomy, facetectomy and foraminotomy; cervical	17.95	17.95	17.95	No.
63046	Laminectomy, facetectomy and foraminotomy; thoracic	17.25	17.25	17.25	No.
657XG ..	Implantation of intrastromal corneal ring segments	NEW	5.93	5.39	No.
68801	Dilation of tear-drainage opening	1	1	0.82	No.
68810	Insertion of probe into the tear duct	2.15	1.54	1.54	No.
68811	Insertion of probe into the tear duct under anesthesia	2.45	2.03	1.74	No.
68815	Probing of nasal-tear duct with insertion of tube or stent	3.3	3	2.7	No.
68816	Probing of nasal-tear duct with balloon catheter dilation	3.06	2.35	2.1	No.
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22	No.
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.22	0.22	No.
7208A ...	Entire spine x ray, one view	NEW	0.3	0.26	No.
7208B ...	Entire spine x-ray; 2 or 3 views	NEW	0.35	0.31	No.
7208C ...	Entire spine x-ray; 4 or 5 views	NEW	0.39	0.35	No.
7208D ...	Entire spine x-ray; min 6 views	NEW	0.45	0.41	No.
73060	Radiologic examination; humerus, minimum of 2 views	0.17	0.16	0.16	No.
73560	Radiologic examination, knee; 1 or 2 views	0.17	0.16	0.16	No.
73562	Radiologic examination, knee; 3 views	0.18	0.18	0.18	No.
73564	Radiologic examination, knee; complete, 4 or more views	0.22	0.22	0.22	No.
73565	Radiologic examination, knee; both knees, standing, anteroposterior.	0.17	0.16	0.16	No.
73590	Radiologic examination; tibia and fibula, 2 views	0.17	0.16	0.16	No.
73600	Radiologic examination, ankle; 2 views	0.16	0.16	0.16	No.
76999	Ultrasound procedure	C	C	C	N/A
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking when performed.	N/A	0.58	0.58	No.
7778B ...	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions.	NEW	1.4	1.4	No.
7778C ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.	NEW	1.95	1.95	No.
7778D ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2–12 channels.	NEW	3.8	3.8	No.
7778E ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels.	NEW	5.4	5.4	No.
88346	Antibody evaluation	0.86	0.74	0.56	No.
8835X ...	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	NEW	0.7	0.53	No.
88367	Morphometric analysis, in situ hybridization (quantitative or semiquantitative), using computer-assisted technology, per specimen: initial single probe stain procedure.	0.73	0.86	0.73	No.
88368	Morphometric analysis, in situ hybridization (quantitative or semiquantitative) manual, per specimen; initial single probe stain procedure.	0.88	0.88	0.88	No.
91299	Procedure for gastrointestinal diagnosis	C	C	C	N/A
9254A ...	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations).	NEW	0.8	0.6	No.
9254B ...	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations).	NEW	0.55	0.3	No.
99174	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral.	N	0	N	No.
9917X ...	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with on-site analysis.	NEW	0	N	No.
G0104 ...	Colorectal cancer screening; flexible sigmoidoscopy	0.96	0.84	0.77	No.
G0105 ...	Colorectal cancer screening; colonoscopy on individual at high risk	3.36	3.36	3.29	No.
G0121 ...	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.	3.36	3.36	3.29	No.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS	Descriptor
20245	Bone biopsy excisional.
20697	Comp ext fixate strut change.
27280	Fusion of sacroiliac joint.
3160A	Bronch ebus 141 gmt. 141 ng 1/2 node.
3160B	Bronch ebus 141 gmt. 141 ng 3/> node.
3160C	Bronch ebus ivntj perph les.
31622	Dx bronchoscope/wash.
31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers.
31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each.
31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl.
3347A	Implant tcat pulm vlv perq.
37215	Transcath stent cca w/eps.
3725A	Intrvasc us noncoronary 1st.
3725B	Intrvasc us noncoronary addl.
38570	Laparoscopy lymph node biop.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS	Descriptor
38571	Laparoscopy lymphadenectomy.
3940A	Mediastinoscpy w/medstnl bx.
3940B	Mediastinoscpy w/lmph nod bx.
44384	Small bowel endoscopy.
44402	Colonoscopy w/stent plcmt.
44403	Colonoscopy w/resection.
44406	Colonoscopy w/ultrasound.
44407	Colonoscopy w/ndl aspir/bx.
44408	Colonoscopy w/decompression.
45337	Sigmoidoscopy & decompress.
45341	Sigmoidoscopy w/ultrasound.
45342	Sigmoidoscopy w/us guide bx.
45347	Sigmoidoscopy w/plcmt stent.
45349	Sigmoidoscopy w/resection.
45389	Colonoscopy w/stent plcmt.
45390	Colonoscopy w/resection.
45391	Colonoscopy w/endoscope us.
45392	Colonoscopy w/endoscopic fnb.
45393	Colonoscopy w/decompression.
47135	Transplantation of liver.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS	Descriptor
5443B	Replantation of penis.
63045	Remove spine lamina 1 crvl.
63046	Remove spine lamina 1 thrc.
68811	Probe nasolacrimal duct.
68815	Probe nasolacrimal duct.
692XX	Remove impacted ear wax uni.
76948	Echo guide ova aspiration.
7778A	Hdr rdncl skn surf brachytx.
7778B	Hdr rdncl skn surf brachytx.
7778C	Hdr rdncl ntrstl/icav brchtx.
7778D	Hdr rdncl ntrstl/icav brchtx.
7778E	Hdr rdncl ntrstl/icav brchtx.
88346	Immunofluorescent study.
8835X	Immunofluor antb addl stain.
9254A	Caloric vstblr test w/rec.
9254B	Caloric vstblr test w/rec.
9935A	Prolong clincl staff svc.
9935B	Prolong clincl staff svc add.

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
10021 ...	Fna w/o image	EF015	mayo stand	NF	.....	24	28	Refined equipment time to conform to established policies for non-highly technical equipment.	.....
		EF023	table, exam	NF	.....	29	28	Refined equipment time to conform to established policies for non-highly technical equipment.	.....
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	1	0	Typically billed with an E/M or other evaluation service.	(0.37)
11750 ...	Removal of nail bed.	EF015	mayo stand	NF	.....	27	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EF031	table, power	NF	.....	54	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	34	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		EQ168	light, exam	NF	.....	54	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	0	2	Refined time to standard time for this clinical labor task.	0.74
		SG067	penrose drain (0.25in x 4in).	NF	.....	1	0	Removed supply not typically used in this service.	(0.50)
11760 ...	Repair of nail bed.	EF014	light, surgical	NF	.....	45	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EF015	mayo stand	NF	.....	45	43	Refined equipment time to conform to established policies for non-highly technical equipment.	.....

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF031	table, power	NF		72	70	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ137	instrument pack, basic ($500–$1,499).	NF		52	47	Refined equipment time to conform to established policies for instrument packs.	(0.01)
		EQ168	light, exam	NF		72	70	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	5	0	Duplication with other clinical labor task.	(1.85)
12005	Rpr s/n/a/gen/trk12.6–20.0cm.	EF023	table, exam	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12006	Rpr s/n/a/gen/trk20.1–30.0cm.	EF031	table, power	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12007	Rpr s/n/ax/gen/trnk >30.0 cm.	EF031	table, power	NF		50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF	.....	50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12013 ...	Rpr f/e/e/n/l/m 2.6–5.0 cm.	EF031	table, power	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12014 ...	Rpr f/e/e/n/l/m 5.1–7.5 cm.	EF031	table, power	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12015 ...	Rpr f/e/e/n/l/m 7.6–12.5 cm.	EF031	table, power	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12016	Rpr fe/e/en/l/m 12.6–20.0 cm.	EF031	table, power	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12041	Intmd rpr n-hf/genit 2.5cm/<.	ED004	camera, digital (6 mexapixel).	F		0	27	Input added to maintain consistency with all other codes within family.	0.10
		ED004	camera, digital (6 mexapixel).	NF		60	27	Refined equipment time to conform to office visit duration.	(0.12)
		EF014	light, surgical	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EF015	mayo stand	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		60	27	Refined equipment time to conform to office visit duration.	(0.10)
		EF031	table, power	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF		0	46	Equipment item replaces another item (EQ138); see preamble.	0.11
		EQ138	instrument pack, medium ($1,500 and up).	NF		40	0	Equipment item replaced by another item (EQ137); see preamble.	(0.28)
		EQ168	light, exam	NF		60	27	Refined equipment time to conform to office visit duration.	(0.14)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
12054	Intmd rpr face/mm 7.6–12.5cm.	ED004	camera, digital (6 mexapixel).	NF		90	27	Refined equipment time to conform to office visit duration.	(0.24)
		EF014	light, surgical	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		90	27	Refined equipment time to conform to office visit duration.	(0.19)
		EF031	table, power	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF		75	80	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF		90	27	Refined equipment time to conform to office visit duration.	(0.27)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
12055	Intmd rpr face/mm 12.6–20 cm.	ED004	camera, digital (6 mexapixel).	NF		136	63	Refined equipment time to conform to office visit duration.	(0.27)
		EF014	light, surgical	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		136	63	Refined equipment time to conform to office visit duration.	(0.22)
		EF031	table, power	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF	.....	85	90	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF	.....	136	63	Refined equipment time to conform to office visit duration.	(0.32)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		SA054	pack, post-op incision care (suture).	F	.....	2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)
12057 ...	Intmd rpr face/mm >30.0 cm.	ED004	camera, digital (6 mexapixel).	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.39)
		EF014	light, surgical	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.31)
		EF031	table, power	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF	.....	115	120	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.45)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		SA054	pack, post-op incision care (suture).	F	.....	2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA054	pack, post-op incision care (suture).	NF	.....	2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)
20240 ...	Bone biopsy excisional.	L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30300 ...	Remove nasal foreign body.	EF008	chair with headrest, exam, reclining.	NF	.....	59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EF015	mayo stand	NF	.....	22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	29	47	Refined equipment time to conform to established policies for instrument packs.	0.04
		EQ167	light source, xenon	F	.....	27	0	Redundant when used together with EQ170; see preamble.	(0.72)
		EQ167	light source, xenon	NF	.....	59	0	Redundant when used together with EQ170; see preamble.	(1.57)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07
		ES013	endoscope, rigid, sinoscopy.	NF	.....	71	74	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	1.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SA041	pack, basic injection.	NF	.....	1	0	Supply item replaced by another item (component parts); see preamble.	(11.67)
		SB001	cap, surgical	NF	.....	0	1	Supply item replaces another item (SA041); see preamble.	0.21
		SB012	drape, sterile, for Mayo stand.	NF	.....	0	1	Supply item replaces another item (SA041); see preamble.	1.69
		SB024	gloves, sterile	NF	.....	0	2	Supply item replaces another item (SA041); see preamble.	1.68
		SB027	gown, staff, impervious.	NF	.....	0	2	Supply item replaces another item (SA041); see preamble.	2.37
		SB033	mask, surgical	NF	.....	0	1	Supply item replaces another item (SA041); see preamble.	0.20
		SB044	underpad 2ft x 3ft (Chux).	NF	.....	0	1	Supply item replaces another item (SA041); see preamble.	0.23
		SG009	applicator, sponge-tipped.	NF	.....	0	3	Supply item replaces another item (SA041); see preamble.	0.42
		SG055	gauze, sterile 4in x 4in.	NF	.....	0	2	Supply item replaces another item (SA041); see preamble.	0.32
		SM010	cleaning brush, endoscope.	F	.....	2	1	Refined supply quantity to what is typical for the procedure.	(4.99)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SM010	cleaning brush, endoscope.	NF	.....	4	2	Refined supply quantity to what is typical for the procedure.	(9.98)
30903 ...	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	54	110	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	54	50	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	61	54	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	54	50	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	54	110	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30905 ...	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	72	128	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	72	68	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	79	72	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	72	68	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	72	128	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30906 ...	Repeat control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	84	140	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	84	80	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	91	84	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	84	80	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	84	140	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
31295 ...	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	50	103	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF015	mayo stand	NF	.....	32	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	42	47	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ167	light source, xenon	NF	.....	50	0	Redundant when used together with EQ170; see preamble.	(1.33)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	50	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	50	103	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF	.....	44	47	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	50	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF	.....	3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
31296 ...	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	60	113	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57
		EF015	mayo stand	NF	.....	60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	52	57	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ167	light source, xenon	NF	.....	60	0	Redundant when used together with EQ170; see preamble.	(1.60)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	60	113	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF	.....	54	57	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF		3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
31297	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF		58	111	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57
		EF015	mayo stand	NF		40	51	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		47	55	Refined equipment time to conform to established policies for instrument packs.	0.02
		EQ167	light source, xenon	NF		58	0	Redundant when used together with EQ170; see preamble.	(1.55)
		EQ170	light, fiberoptic headlight w-source.	NF		58	51	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		58	111	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF		52	55	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		58	51	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF		3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
38572	Laparoscopy lymphadenectomy.	SA051	pack, pelvic exam	F		1	0	Removed supply not typically used in this service.	(1.17)
40804	Removal foreign body mouth.	EF008	chair with headrest, exam, reclining.	NF		74	82	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		29	39	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	36	38	Refined equipment time to conform to established policies for instrument packs.	—
		EQ170	light, fiberoptic headlight w-source.	NF	.....	74	82	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		EQ234	suction and pressure cabinet, ENT (SMR).	F	.....	27	0	Equipment usage not typical for a follow-up office visit.	(0.25)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	61	39	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.20)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SD009	canister, suction	NF	.....	2	1	Refined supply quantity to what is typical for the procedure.	(3.91)
42809 ...	Remove pharynx foreign body.	EF008	chair with headrest, exam, reclining.	NF	.....	58	74	Refined equipment time to conform to established policies for non-highly technical equipment.	0.17
		EF015	mayo stand	NF	.....	26	47	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	60	51	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	58	74	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ234	suction and pressure cabinet, ENT (SMR).	F	.....	27	0	Equipment usage not typical for a follow-up office visit.	(0.25)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	58	47	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.10)
		ES020	fiberscope, flexible, rhinolaryngoscopy.	NF	.....	115	128	Refined equipment time to conform to established policies for scopes.	0.47
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SA048	pack, minimum multi-specialty visit.	F	.....	2	1	Refined supply quantity to what is typical for the procedure.	(1.14)
44380 ...	Small bowel endoscopy br/wa.	EF018	stretcher	NF	.....	73	77	Standard time for moderate sedation equipment.	0.02
		EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
44381 ...	Small bowel endoscopy br/wa.	EF018	stretcher	NF	.....	83	87	Standard equipment and time for moderate sedation.	0.02
		EF027	table, instrument, mobile.	NF	.....	39	87	Standard equipment and time for moderate sedation.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	87	Standard equipment and time for moderate sedation.	0.35

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ032	IV infusion pump ...	NF	.....	62	87	Standard equipment and time for moderate sedation.	0.16
44382 ...	Small bowel endoscopy.	EF018	stretcher	NF	.....	78	82	Standard time for moderate sedation equipment.	0.02
		EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
44385 ...	Endoscopy of bowel pouch.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
44386 ...	Endoscopy bowel pouch/biop.	EF027	table, instrument, mobile.	NF	.....	31	79	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	31	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.51)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	54	79	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	54	79	Standard time for moderate sedation equipment.	0.16
44388 ...	Colonoscopy thru stoma spx.	EF027	table, instrument, mobile.	NF	.....	57	87	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	39	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.64)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	87	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	57	87	Standard time for moderate sedation equipment.	0.19
44389 ...	Colonoscopy with biopsy.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard time for moderate sedation equipment.	0.19
44390 ...	Colonoscopy for foreign body.	EF027	table, instrument, mobile.	NF	.....	67	97	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	67	97	Standard time for moderate sedation equipment.	0.19
44391 ...	Colonoscopy for bleeding.	EF027	table, instrument, mobile.	NF	.....	72	102	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	54	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.88)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	72	102	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	72	102	Standard time for moderate sedation equipment.	0.19
44392 ...	Colonoscopy & polypectomy.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard time for moderate sedation equipment.	0.19
44394 ...	Colonoscopy w/ snare.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard time for moderate sedation equipment.	0.19
44401 ...	Colonoscopy with ablation.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF	.....	44	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.19
44404 ...	Colonoscopy w/ injection.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.04
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard equipment and time for moderate sedation.	0.19
44405 ...	Colonoscopy w/ dilation.	EF027	table, instrument, mobile.	NF	.....	40	100	Standard equipment and time for moderate sedation.	0.08
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	50	100	Standard equipment and time for moderate sedation.	0.70
		EQ032	IV infusion pump ...	NF	.....	50	100	Standard equipment and time for moderate sedation.	0.32
45330 ...	Diagnostic sigmoidoscopy.	EF027	table, instrument, mobile.	NF	.....	12	0	No moderate sedation	(0.02)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	18	0	No moderate sedation	(0.25)
		EQ235	suction machine (Gomco).	NF	.....	12	22	Increased to reflect Intra-Service clinical labor tasks.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	12	22	Increased to reflect Intra-Service clinical labor tasks.	1.29
		ES043	Video Sigmoidoscope.	NF	.....	42	49	Refined equipment time to conform to established policies for scopes.	0.49
45331 ...	Sigmoidoscopy and biopsy.	EF027	table, instrument, mobile.	NF	.....	12	0	No moderate sedation	(0.02)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	33	0	No moderate sedation	(0.46)
		EQ235	suction machine (Gomco).	NF	.....	12	27	Matches time spent using endoscope system.	0.03
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	12	27	Increased to reflect Intra-Service clinical labor tasks.	1.93
		ES043	Video Sigmoidoscope.	NF	.....	42	54	Refined equipment time to conform to established policies for scopes.	0.83
45332 ...	Sigmoidoscopy w/fb removal.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
45333 ...	Sigmoidoscopy & polypectomy.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
45334 ...	Sigmoidoscopy for bleeding.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
45335 ...	Sigmoidoscopy w/submuc inj.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
45338 ...	Sigmoidoscopy w/tumr remove.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
45340 ...	Sig w/tndsc balloon dilation.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
45346 ...	Sigmoidoscopy w/ablation.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard equipment and time for moderate sedation.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard equipment and time for moderate sedation.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard equipment and time for moderate sedation.	0.16
45350 ...	Sgmdsc w/band ligation.	EF027	table, instrument, mobile.	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.02)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.17)
		EQ032	IV infusion pump ...	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.08)
		SH074	water, sterile for irrigation (250–1000ml uou).	NF	.....	1	0	This input is not contained within any other code in this family; maintaining consistency with all other codes within family.	(2.09)
		SK087	water, distilled	NF	.....	0	5	This input is not contained within any other code in this family; maintaining consistency with all other codes within family.	0.07
45378 ...	Diagnostic colonoscopy.	EF027	table, instrument, mobile.	NF	.....	57	87	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	39	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.64)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	87	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	57	87	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	72	39	Matches time spent using endoscope system.	(0.07)
45379 ...	Colonoscopy w/fb removal.	EF027	table, instrument, mobile.	NF	.....	67	97	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	67	97	Standard time for moderate sedation equipment.	0.19

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ235	suction machine (Gomco).	NF		92	49	Matches time spent using endoscope system.	(0.08)
45380 ...	Colonoscopy and biopsy.	EF027	table, instrument, mobile.	NF		60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		78	42	Matches time spent using endoscope system.	(0.07)
45381 ...	Colonoscopy submucous njx.	EF027	table, instrument, mobile.	NF		60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		78	42	Matches time spent using endoscope system.	(0.07)
45382 ...	Colonoscopy w/ control bleed.	EF027	table, instrument, mobile.	NF		72	102	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		54	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.88)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		72	102	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		72	102	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		102	54	Matches time spent using endoscope system.	(0.09)
45384 ...	Colonoscopy w/ lesion removal.	EF027	table, instrument, mobile.	NF		60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		78	42	Matches time spent using endoscope system.	(0.07)
45385 ...	Colonoscopy w/ lesion removal.	EF027	table, instrument, mobile.	NF		62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		62	92	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		82	44	Matches time spent using endoscope system.	(0.07)
45386 ...	Colonoscopy w/ balloon dilat.	EF027	table, instrument, mobile.	NF		67	97	Standard time for moderate sedation equipment.	0.04

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF031	table, power	NF		49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		67	97	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		92	49	Matches time spent using endoscope system.	(0.08)
45388	Colonoscopy w/ ablation.	EF027	table, instrument, mobile.	NF		67	97	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF		49	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		67	97	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		67	97	Standard equipment and time for moderate sedation.	0.19
		EQ235	suction machine (Gomco).	NF		92	49	Matches time spent using endoscope system.	(0.08)
45398	Colonoscopy w/ band ligation.	EF027	table, instrument, mobile.	NF		52	82	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF		34	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		52	82	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		52	82	Standard equipment and time for moderate sedation.	0.19
		EQ235	suction machine (Gomco).	NF		62	34	Matches time spent using endoscope system.	(0.06)
46500	Injection into hemorrhoid(s).	EF014	light, surgical	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.13)
		EF031	table, power	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.21)
		EQ235	suction machine (Gomco).	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		ES002	anoscope with light source.	NF		78	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.07)
		L037D	RN/LPN/MTA	F	Cleaning scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Setup scope at POV.	5	0	Included in clinical labor task ''Prepare room, equipment, supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	NF	Clean scope	5	0	Included in clinical labor task ''Clean room, equipment, and supplies''.	(1.85)
		L037D	RN/LPN/MTA	NF	Cleaning scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Typically billed with an E/M or other evaluation service.	(1.11)
		L037D	RN/LPN/MTA	NF	Setup scope (non facility setting only).	5	0	Included in clinical labor task ''Prepare room, equipment, supplies''.	(1.85)
		L037D	RN/LPN/MTA	NF	Setup scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		2	0	Removed supply associated with equipment item not typically used in this service.	(34.12)
46601	Diagnostic anoscopy.	EF031	table, power	NF		41	33	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.13)
46607	Diagnostic anoscopy & biopsy.	EF031	table, power	NF		49	38	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.18)
5039A	Njx px nfrosgrm &/urtrgrm.	ED050	PACS Workstation Proxy.	NF		58	67	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		284	277	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		44	0	Equipment item replaced by another item; see preamble.	(231.21)
		EL014	room, radiographic-fluoroscopic.	NF		0	44	Equipment item replaces another item; see preamble.	61.30
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		284	277	Standard equipment and time for moderate sedation.	(0.10)
		EQ032	IV infusion pump	NF		284	277	Standard equipment and time for moderate sedation.	(0.04)
		EQ168	light, exam	NF		44	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L051A	RN	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; a similar item is already included in this service.	(1.60)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way ...	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5039B ...	Njx px nfrosgrm &/urtrgrm.	ED050	PACS Workstation Proxy.	NF	.....	21	45	Refined equipment time to conform to clinical labor time (Full intraservice period minus monitoring time).	0.53
		EF027	table, instrument, mobile.	NF	.....	22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		EL011	room, angiography	NF	.....	22	0	Equipment item replaced by another item; see preamble.	(115.60)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	22	Equipment item replaces another item; see preamble.	30.65
		EQ168	light, exam	NF	.....	22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		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)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB001	cap, surgical	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.21)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB033	mask, surgical	NF	.....	2	1	Aligned supply quantities with changes to number of clinical labor staff.	(0.20)
		SB039	shoe covers, surgical.	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.34)
5039C ..	Plmt nephrostomy catheter.	ED050	PACS Workstation Proxy.	NF	.....	71	80	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF	.....	300	290	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF	.....	60	0	Equipment item replaced by another item; see preamble.	(315.28)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	60	Equipment item replaces another item; see preamble.	83.59
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	300	290	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump ...	NF	.....	300	290	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF	.....	60	75	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5039D ..	Plmt nephroureteral catheter.	ED050	PACS Workstation Proxy.	NF		83	92	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		312	302	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		72	0	Equipment item replaced by another item; see preamble.	(378.34)
		EL014	room, radiographic-fluoroscopic.	NF		0	72	Equipment item replaces another item; see preamble.	100.30
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		312	302	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		312	302	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		72	87	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; a similar item is already included in this service.	(1.60)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way ...	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
		SD306	Nephroureteral Catheter.	NF	.....	1	0	Supply not mentioned in SOR work description.	(117.90)
5039E ...	Exchange nephrostomy cath.	ED050	PACS Workstation Proxy.	NF	.....	21	50	Refined equipment time to conform to clinical labor time.	0.64
		EF027	table, instrument, mobile.	NF	.....	90	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EL011	room, angiography	NF	.....	30	0	Equipment item replaced by another item; see preamble.	(157.64)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	30	Equipment item replaces another item; see preamble.	41.79
		EQ168	light, exam	NF	.....	30	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	20	0	Clinical labor type replaced by another labor type; see preamble.	(7.40)
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		SA031	kit, suture removal	NF	.....	1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB001	cap, surgical	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.21)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB033	mask, surgical	NF	.....	2	1	Aligned supply quantities with changes to number of clinical labor staff.	(0.20)
		SB039	shoe covers, surgical.	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.34)
5039M ..	Convert nephrostomy catheter.	ED050	PACS Workstation Proxy.	NF	.....	68	77	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF	.....	57	0	Equipment item replaced by another item; see preamble.	(299.52)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	57	Equipment item replaces another item; see preamble.	79.41
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump ...	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.06)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ168	light, exam	NF		57	72	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA031	kit, suture removal	NF		1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069G	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF		68	77	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		297	287	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		57	0	Equipment item replaced by another item; see preamble.	(299.52)
		EL014	room, radiographic-fluoroscopic.	NF		0	57	Equipment item replaces another item; see preamble.	79.41
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		297	287	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		297	287	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		57	72	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA031	kit, suture removal	NF		1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069H	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF		85	94	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		314	304	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		74	0	Equipment item replaced by another item; see preamble.	(388.85)
		EL014	room, radiographic-fluoroscopic.	NF		0	74	Equipment item replaces another item; see preamble.	103.09
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		314	304	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		314	304	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		74	89	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Acquire images (75%).	47	46	Rounding error in CL time calculation.	(0.41)
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF	.....	2	1	Duplicative; a similar item is already included in this service.	(4.67)
		SC049	stop cock, 3-way ...	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069I	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF	.....	98	107	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF	.....	327	317	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF	.....	87	0	Equipment item replaced by another item; see preamble.	(457.16)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	87	Equipment item replaces another item; see preamble.	121.20
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	327	317	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump ...	NF	.....	327	317	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF	.....	87	102	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way ...	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5443A ...	Repair corporeal tear.	EF031	table, power	F	.....	144	135	Refined equipment time to conform to clinical labor time.	(0.15)
		EF031	table, power	NF	.....	144	135	Refined equipment time to conform to clinical labor time.	(0.15)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ168	light, exam	F		144	135	Refined equipment time to conform to clinical labor time.	(0.04)
		EQ168	light, exam	NF		144	135	Refined equipment time to conform to clinical labor time.	(0.04)
657XG	Impltj ntrstrml crnl rng seg.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68801	Dilate tear duct opening.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68810	Probe nasolacrimal duct.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68816	Probe nl duct w/ balloon.	EL006	lane, screening (oph).	NF		16	47	Refined equipment time to conform to clinical labor time.	2.77
69200	Clear outer ear canal.	EF008	chair with headrest, exam, reclining.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		EF015	mayo stand	NF		19	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		26	31	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ170	light, fiberoptic headlight w-source.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
		EQ183	microscope, operating.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		5	0	Supply item replaced by another item (SH050); see preamble.	(0.18)
		SH050	lidocaine 4% soln, topical (Xylocaine).	NF		0	3	Supply item replaces another item (SH047); see preamble.	0.46
69220	Clean out mastoid cavity.	EF008	chair with headrest, exam, reclining.	NF		20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		EF015	mayo stand	NF		17	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		0	29	Equipment item replaces another item (EQ138); see preamble.	0.07
		EQ138	instrument pack, medium ($1,500 and up).	NF		29	0	Equipment item replaced by another item (EQ137); see preamble.	(0.20)
		EQ183	microscope, operating.	NF		20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.14

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		L037D	RN/LPN/MTA	F	Dischrg day gmt. (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Clean surgical instrument package.	15	10	Refined time to standard time for this clinical labor task.	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/ obtain consent.	0	2	Refined time to standard time for this clinical labor task.	0.74
7208A ...	X-ray exam entire spi 1 vw.	ED050	PACS Workstation Proxy.	NF	.....	21	25	Refined equipment time to conform to clinical labor time.	0.09
7208B ...	X-ray exam entire spi 2/3 vw.	ED050	PACS Workstation Proxy.	NF	.....	36	40	Refined equipment time to conform to clinical labor time.	0.09
7208C ..	X-ray exam entire spi 4/5 vw.	ED050	PACS Workstation Proxy.	NF	.....	44	48	Refined equipment time to conform to clinical labor time.	0.09
7208D ..	X-ray exam entire spi 6/ vw.	ED050	PACS Workstation Proxy.	NF	.....	53	57	Refined equipment time to conform to clinical labor time.	0.09
73565 ...	X-ray exam of knees.	L041B	Radiologic Technologist.	NF	Greet patient and provide gowning.	0	3	Input added to maintain consistency with all other codes within family.	1.23
77385 ...	Ntsty modul rad tx dlvr smpl.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	27	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.10)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77386 ...	Ntsty modul rad tx dlvr cplx.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	42	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.15)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		ER102	Power conditioner ..	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
		L050C	Radiation Therapist	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	1	Refined to conform with identical labor activity in other codes in the family.	(0.50)
77402 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	12	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.04)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77407 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	17	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.06)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77412 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	21	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.08)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		ER089	IMRT accelerator ...	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
88104 ...	Cytopath fl nongyn smears.	EP024	microscope, compound.	NF	.....	60	56	Refined to conform with identical labor activity in other codes in the family.	(0.15)
		L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88106 ...	Cytopath fl nongyn filter.	L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88108 ...	Cytopath concentrate tech.	L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88160 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)
		L035A	Lab Tech/ Histotechnologist.	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
		L035A	Lab Tech/ Histotechnologist.	NF	Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination).	5	0	See preamble text	(1.75)
88161 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination).	5	3	Refined time to standard time for this clinical labor task.	(0.70)
88162 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Other Clinical Activity (please specify): Prepare automated stainer with solutions and load microscopic slides.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
88182 ...	Cell marker study.	L033A	Lab Technician	NF	Accession specimen/prepare for examination.	6	4	Refined time to standard time for this clinical labor task.	(0.66)
	Cell marker study.	L033A	Lab Technician	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L045A	Cytotechnologist	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.45)
		L045A	Cytotechnologist	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	2	0	Refined time to standard time for this clinical labor task.	(0.90)
		L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist.	5	2	Refined time to standard time for this clinical labor task.	(1.35)
88184 ...	Flowcytometry/ tc 1 marker.	ED031	printer, dye sublimation (photo, color).	NF	.....	5	1	Refined equipment time to conform to clinical labor time.	(0.04)
		L033A	Lab Technician	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.33)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	4	0	Refined time to standard time for this clinical labor task.	(1.32)
		L045A	Cytotechnologist	NF	Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling.	15	13	Refined to conform with identical labor activity in other codes in the family.	(0.90)
		L045A	Cytotechnologist	NF	Other Clinical Activity (please specify) Load specimen into flow cytometer, run specimen, monitor data acquisition, and.	10	7	Refined to conform with identical labor activity in other codes in the family.	(1.35)
		L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist.	5	2	Refined time to standard time for this clinical labor task.	(1.35)
88185 ...	Flowcytometry/tc add-on.	ED031	printer, dye sublimation (photo, color).	NF	.....	2	1	Refined equipment time to conform to clinical labor time.	(0.01)
		L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	1	0	Refined time to standard time for this clinical labor task.	(0.33)
88321 ...	Microslide consultation.	L033A	Lab Technician	NF	Accession specimen/prepare for examination.	4	0	Duplication with other clinical labor task.	(1.32)
		L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	See preamble text	(2.64)
		L037B	Histotechnologist ...	NF	Phone calls for clarifications and/or additional materials.	0	3	Input added to maintain consistency with all other codes within family.	1.11
88323 ...	Microslide consultation.	L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	Non-standard refinement, see preamble text.	(2.64)
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	1	0	Duplication with other clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Clean equipment while performing service.	1	0	Duplication with other clinical labor task.	(0.37)
		SL063	eosin y	NF	.....	8	0	Redundant when used together with SL135.	(6.41)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SL135	stain, hematoxylin ..	NF	.....	32	8	Refined supply quantity to what is typical for the procedure.	(1.06)
88325 ...	.....	EP019	hood, ventilator with blower.	NF	.....	1	0	See preamble text	—
		EP033	slide coverslipper, robotic.	NF	.....	6	0	See preamble text	(0.57)
		EP034	slide dryer	NF	.....	1	0	See preamble text	—
		EP035	slide etcher-labeler	NF	.....	1	0	See preamble text	(0.05)
		EP036	slide stainer, automated, high-volume throughput.	NF	.....	12	0	See preamble text	(0.55)
		EP038	solvent recycling system.	NF	.....	4	0	See preamble text	(0.18)
		EP043	water bath, general purpose (lab).	NF	.....	6	0	See preamble text	(0.01)
		ER041	microtome	NF	.....	6	0	See preamble text	(0.26)
		L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stain.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(3.30)
		L033A	Lab Technician	NF	Accession specimen/prepare for examination.	4	0	Duplication with other clinical labor task.	(1.32)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	1	0	See preamble text	(0.33)
		L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	See preamble text	(2.64)
		L033A	Lab Technician	NF	prepare, pack and transport specimens and records for in-house storage and external storage.	2	0	See preamble text	(0.66)
		L037B	Histotechnologist ...	NF	Clean equipment while performing service.	1	0	Duplication with other clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	1	0	See preamble text	(0.37)
		L037B	Histotechnologist ...	NF	Prepare automated coverslipper, remove slides from stainer and place on coverslipper.	1	0	See preamble text	(0.37)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	1	0	See preamble text	(0.37)
		L037B	Histotechnologist ...	NF	Slide preparation sectioning and recuts, quality control function, maintaining specimen tracking, logs and labeling.	4	0	See preamble text	(1.48)
		SB023	gloves, non-sterile, nitrile.	NF	.....	2	0	See preamble text	(0.38)
		SB027	gown, staff, impervious.	NF	.....	0.1	0	See preamble text	(0.12)
		SF004	blade, microtome ...	NF	.....	0.2	0	See preamble text	(0.34)
		SL020	bleach	NF	.....	10	0	See preamble text	(0.01)
		SL030	cover slip, glass	NF	.....	2	0	See preamble text	(0.16)
		SL063	eosin y	NF	.....	8	0	See preamble text	(6.41)
		SL078	histology freezing spray (Freeze-It).	NF	.....	0.2	0	See preamble text	(0.29)
		SL085	label for microscope slides.	NF	.....	20	10	See preamble text	(0.26)
		SL095	mounting media (Histomount).	NF	.....	2	0	See preamble text	(0.07)
		SL122	slide, microscope ...	NF	.....	2	0	See preamble text	(0.11)
		SL135	stain, hematoxylin ..	NF	.....	32	0	See preamble text	(1.41)
		SL151	xylenes solvent	NF	.....	60	0	See preamble text	(0.72)
		SL189	ethanol, 100%	NF	.....	60	0	See preamble text	(0.20)
		SL190	ethanol, 70%	NF	.....	8	0	See preamble text	(0.03)
		SL248	ethanol, 95%	NF	.....	36	0	See preamble text	(0.12)
		SM027	wipes, lens cleaning (per wipe) (Kimwipe).	NF	.....	2	0	See preamble text	(0.03)
88329 ...	Path consult introp.	L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	10	3	Refined time to standard time for this clinical labor task.	(2.59)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	5	1	Refined time to standard time for this clinical labor task.	(1.48)
88331 ...	Path consult intraop 1 bloc.	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stai.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	1.48
		L037B	Histotechnologist ...	NF	Accession specimen/prepare for examination.	0	4	Input added to maintain consistency with all other codes within family.	1.48
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	10	3	Refined time to standard time for this clinical labor task.	(2.59)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	10	1	Refined time to standard time for this clinical labor task.	(3.33)
		SL134	stain, frozen section, H&E (1ml per slide).	NF	.....	0	1	Supply item replaces another item (SL231); see preamble.	0.57
		SL231	kit, stain, H&E	NF	.....	0.1	0	Supply item replaced by another item (SL134); see preamble.	(9.80)
88332 ...	Path consult intraop addl.	L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	2	3	Refined time to standard time for this clinical labor task.	0.37
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	0	1	Input added to maintain consistency with all other codes within family.	0.37
		SF047	scalpel, safety, surgical, with blade (#10–20).	NF	.....	0	1	Input added to maintain consistency with all other codes within family.	2.14
		SL134	stain, frozen section, H&E (1ml per slide).	NF	.....	0	1	Supply item replaces another item (SL231); see preamble.	0.57
		SL231	kit, stain, H&E	NF	.....	0.1	0	Supply item replaced by another item (SL134); see preamble.	(9.80)
88333 ...	Intraop cyto path consult 1.	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stai.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(3.30)
		L037B	Histotechnologist ...	NF	Accession specimen/prepare for examination.	0	4	Input added to maintain consistency with all other codes within family.	1.48
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination (including performance of intraoperative frozen sections).	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	5	1	Refined time to standard time for this clinical labor task.	(1.48)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SL122	slide, microscope ...	NF	.....	10	4	Refined supply quantity to what is typical for the procedure.	(0.33)
		SL231	kit, stain, H&E	NF	.....	0.1	0	Removed supply not typically used in this service.	(9.80)
88334 ...	Intraop cyto path consult 2.	L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination (including performance of intraoperative frozen sections).	5	3	Refined time to standard time for this clinical labor task.	(0.74)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	0	1	Input added to maintain consistency with all other codes within family.	0.37
		SL122	slide, microscope ...	NF	.....	10	4	Refined supply quantity to what is typical for the procedure.	(0.33)
		SL231	kit, stain, H&E	NF	.....	0.1	0	Removed supply not typically used in this service.	(9.80)
88355 ...	Analysis skeletal muscle.	EP046	freezer, ultradeep (−70 degrees).	NF	.....	30	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(1.32)
		L033A	Lab Technician	NF	Accession specimen/prepare for examination.	6	4	Refined time to standard time for this clinical labor task.	(0.66)
		L033A	Lab Technician	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L033A	Lab Technician	NF	Clean room, equipment following procedure including any equipment maintenance that must be done after the procedure.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.	9	0.5	Refined time to standard time for this clinical labor task.	(2.81)
		L033A	Lab Technician	NF	Prepare specimen for −70 degree storage, log specimen and place in freezer for retrieval and performance of quantitative.	5	0	Refined time to standard time for this clinical labor task.	(1.65)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Prepare, pack and transport specimens and records for storage.	4	1	Refined time to standard time for this clinical labor task.	(0.99)
		L033A	Lab Technician	NF	Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen p.	7	5	See preamble text	(0.66)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross examination.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
88360 ...	Tumor immunohistochem/manual.	EP024	microscope, compound.	NF	.....	36	25	See preamble text	(0.41)
		L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	Non-standard clinical labor task.	(0.33)
		L037B	Histotechnologist ...	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for.	5	1	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Verify results and complete work load recording logs.	1	0	Refined time to standard time for this clinical labor task.	(0.37)
88361 ...	Tumor immunohistochem/comput.	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	Non-standard clinical labor task.	(0.33)
		L037B	Histotechnologist ...	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for.	5	1	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Verify results and complete work load recording logs.	1	0	Refined time to standard time for this clinical labor task.	(0.37)
88362 ...	Nerve teasing preparations.	L033A	Lab Technician	NF	Assemble and deliver cedar mounted slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L033A	Lab Technician	NF	Assemble other light microscopy slides, epon nerve biopsy slides, and clinical history, and present to pathologist to pr.	5	0.5	Refined time to standard time for this clinical labor task.	(1.49)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Clean room/ equipment following procedure (including dissecting microscope and dissection work area. Cedar oil specific c.	7	1	Refined time to standard time for this clinical labor task.	(1.98)
		L033A	Electrodiagnostic Technologist.	NF	Preparation: labeling of blocks and containers and document location and processor used.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L037B	Histotechnologist ...	NF	Accession specimen and prepare for examination.	10	4	Refined time to standard time for this clinical labor task.	(2.22)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination including the following; A ; Selection of fresh unfixed tissue samp.	10	5	Non-standard refinement, see preamble text.	(1.85)
		L037B	Histotechnologist ...	NF	Consult with pathologist regarding representation needed, block selection and appropriate technique.	7	0	Task would not be required for the typical procedure.	(2.59)
		L037B	Histotechnologist ...	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Manage any relevant utilization review/quality assurance activities and regulatory compliance documentation.	2	0	Refined time to standard time for this clinical labor task.	(0.74)
		L037B	Histotechnologist ...	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician.	12	0.5	Refined time to standard time for this clinical labor task.	(4.26)
		L037B	Histotechnologist ...	NF	Prepare, pack and transport cedar oiled glass slides and records for in-house special storage (need to be stored flat).	10	0	Refined time to standard time for this clinical labor task.	(3.70)
		L037B	Histotechnologist ...	NF	Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).	2	1	Refined time to standard time for this clinical labor task.	(0.37)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Storage remaining specimen. (Osmicated nerve strands, potential for additional teased specimens).	5	0	Refined time to standard time for this clinical labor task.	(1.85)
92511 ...	Nasopharyngoscopy.	EF008	chair with headrest, exam, reclining.	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EQ167	light source, xenon	NF	.....	19	0	Redundant when used together with EQ170; see preamble.	(0.51)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		ES020	fiberscope, flexible, rhinolaryngoscopy.	NF	.....	46	53	Refined equipment time to conform to established policies for scopes.	0.26
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.90
		L037D	RN/LPN/MTA	F	Dischrge Day mgmt. (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SB006	drape, non-sterile, sheet 40in x 60in.	NF	.....	1	0	Removed supply not typically used in this service.	(0.22)
		SB027	gown, staff, impervious.	NF	.....	2	0	Removed supply not typically used in this service.	(2.37)
		SB033	mask, surgical	NF	.....	2	0	Removed supply not typically used in this service.	(0.39)
		SD070	endosheath	NF	.....	1	0	Removed supply not typically used in this service.	(17.25)
95812 ...	Eeg 41–60 minutes.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	124	99	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.15)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	133	99	Refined equipment time to conform to established policies for non-highly technical equipment.	(4.99)
		L047B	REEGT	NF	Assist physician in performing procedure.	79	50	Refined clinical labor time to match physician intraservice time.	(13.63)
		L047B	REEGT	NF	Enter patient information into laboratory log book.	2	0	Refined to conform with identical labor activity in other codes in the family.	(0.94)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)
		L047B	REEGT	NF	Transfer data to reading station & archive data.	4	2	Refined time to standard time for this clinical labor task.	(0.94)
95813 ...	Eeg over 1 hour	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	147	129	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.11)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	156	129	Refined equipment time to conform to established policies for non-highly technical equipment.	(3.96)
		L047B	REEGT	NF	Assist physician in performing procedure.	102	80	Refined clinical labor time to match physician intraservice time.	(10.34)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L047B	REEGT	NF	Enter patient information into laboratory log book.	2	0	Refined to conform with identical labor activity in other codes in the family.	(0.94)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)
		L047B	REEGT	NF	Transfer data to reading station & archive data.	4	2	Refined time to standard time for this clinical labor task.	(0.94)
95863	Muscle test 3 limbs.	EF023	table, exam	NF		52	55	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		52	55	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
95864	Muscle test 4 limbs.	EF023	table, exam	NF		62	65	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		62	65	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Other Clinical Activity—specify:Prepare technician report, summarize clinical and electrodiagnostic data, and interpre.	6	0	Refined to conform with identical labor activity in other codes in the family.	(2.22)
95869	Muscle test thor paraspinal.	EF023	table, exam	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
95870	Muscle test nonparaspinal.	EF023	table, exam	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
		SD275	Disposable electrode pack.	NF		6	1	Refined supply quantity to what is typical for the procedure.	(13.75)
95923	Autonomic nrv syst funj test.	EF023	table, exam	NF		51	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EQ035	QSART acquisition system (Q-Sweat).	NF		46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.33)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ124	stimulator, constant current, w-stimulating and grounding electrodes (Grass Telefactor).	NF	.....	46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ171	light, infra-red, ceiling mount.	NF	.....	46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	.....
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	5	0	Typically billed with an E/M or other evaluation service.	(1.85)
		L037A	Electrodiagnostic Technologist.	NF	Complete diagnostic forms, lab & X-ray requisitions.	5	0	Typically billed with an E/M or other evaluation service.	(1.85)
		L037A	Electrodiagnostic Technologist.	NF	Complete preservice diagnostic & referral forms.	5	2	Refined to conform with identical labor activity in other codes in the family.	(1.11)
		L037A	Electrodiagnostic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Refined time to standard time for this clinical labor task.	0.74
		SA014	kit, electrode, iontophoresis.	NF	.....	4	3	See preamble text	(4.01)
		SA048	pack, minimum multi-specialty visit.	NF	.....	1	0	Typically billed with an E/M or other evaluation service.	(1.14)
95928 ...	C motor evoked uppr limbs.	EF023	table, exam	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ024	EMG–NCV–EP system, 8 channel.	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(2.95)
		EQ178	magnetic stimulator hand coil (70–90mm).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.16)
		EQ180	magnetic stimulator system (BiStim).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(1.43)
		L047B	REEGT	NF	Assist physician in performing procedure.	60	40	Refined clinical labor time to match physician intraservice time.	(9.40)
		L047B	REEGT	NF	Other Clinical Activity—specify: Review requisition. Assess for special needs. Give patient instructions for test prepa.	3	0	Duplication with other clinical labor task.	(1.41)
		SA048	pack, minimum multi-specialty visit.	NF	.....	1	0	Typically billed with an E/M or other evaluation service.	(1.14)
95929 ...	C motor evoked lwr limbs.	EF023	table, exam	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ024	EMG–NCV–EP system, 8 channel.	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(2.95)
		EQ179	magnetic stimulator leg coil (110mm).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.24)
		EQ180	magnetic stimulator system (BiStim).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(1.43)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L047B	REEGT	NF	Assist physician in performing procedure.	60	40	Refined clinical labor time to match physician intraservice time.	(9.40)
		L047B	REEGT	NF	Other Clinical Activity—specify:Review requisition. Assess for special needs. Give patient instructions for test prepa.	3	0	Duplication with other clinical labor task.	(1.41)
95933	Blink reflex test	L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
		L037A	Electrodiagnostic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Refined time to standard time for this clinical labor task.	0.74
95956	Eeg monitor technol attended.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF		772	769	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF		772	769	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.44)
		EQ047	air compressor, safety.	NF		52	49	Refined equipment time to conform to established policies for non-highly technical equipment.	
		L047B	REEGT	NF	Other Clinical Activity—specify: Coordinate pretesting services/review test/exam results.	3	0	Duplication with other clinical labor task.	(1.41)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES MALPRACTICE RVUS

CY 2016 New, Revised or Potentially Misvalued Code		Malpractice Risk Factor Crosswalk Code	
11750	Removal of nail bed	11750	Removal of nail bed.
20240	Bone biopsy excisional	20240	Bone biopsy excisional.
27280	Fusion of sacroiliac joint	27280	Fusion of sacroiliac joint.
31622	Dx bronchoscope/wash	31622	Dx bronchoscope/wash.
3160A	Bronch ebus sampling 1/2 node	31620	Endobronchial us add-on.
3160B	Bronch ebus samplng 3/≤ node	31620	Endobronchial us add-on.
31625	Bronchoscopy w/biopsy(s)	31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers	31626	Bronchoscopy w/markers.
31628	Bronchoscopy/lung bx each	31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each	31629	Bronchoscopy/needle bx each.
3160C	Bronch ebus ivntj perph les	31620	Endobronchial us add-on.
31632	Bronchoscopy/lung bx addl	31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl	31633	Bronchoscopy/needle bx addl.
3347A	Implant tcat pulm vlv perq	93581	Transcath closure of vsd.
3725A	Intrvasc us noncoronary 1st	37250	Iv us first vessel add-on.
3725B	Intrvasc us noncoronary addl	37251	Iv us each add vessel add-on.
38570	Laparoscopy lymph node biop	38570	Laparoscopy lymph node biop.
38571	Laparoscopy lymphadenectomy	38571	Laparoscopy lymphadenectomy.
38572	Laparoscopy lymphadenectomy	38572	Laparoscopy lymphadenectomy.
3940A	Mediastinoscpy w/medstnl bx	33924	Remove pulmonary shunt.
3940B	Mediastinoscpy w/lmph nod bx	32606	Thoracoscopy w/bx med space.
44380	Small bowel endoscopy br/wa	44380	Small bowel endoscopy br/wa.
44381	Small bowel endoscopy br/wa	45340	Sig w/tndsc balloon dilation.
44382	Small bowel endoscopy	44382	Small bowel endoscopy.

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES
MALPRACTICE RVUs—Continued

44384	Small bowel endoscopy	44383	Ileoscopy w/stent.
44385	Endoscopy of bowel pouch	44385	Endoscopy of bowel pouch.
44386	Endoscopy bowel pouch/biop	44386	Endoscopy bowel pouch/biop.
44388	Colonoscopy thru stoma spx	44388	Colonoscopy thru stoma spx.
44389	Colonoscopy with biopsy	44389	Colonoscopy with biopsy.
44390	Colonoscopy for foreign body	44390	Colonoscopy for foreign body.
44391	Colonoscopy for bleeding	44391	Colonoscopy for bleeding.
44392	Colonoscopy & polypectomy	44392	Colonoscopy & polypectomy.
44394	Colonoscopy w/snare	44394	Colonoscopy w/snare.
44401	Colonoscopy with ablation	44393	Colonoscopy lesion removal.
44402	Colonoscopy w/stent plcmt	44397	Colonoscopy w/stent.
44403	Colonoscopy w/resection	44392	Colonoscopy & polypectomy.
44404	Colonoscopy w/injection	44389	Colonoscopy with biopsy.
44405	Colonoscopy w/dilation	44390	Colonoscopy for foreign body.
44406	Colonoscopy w/ultrasound	44394	Colonoscopy w/snare.
45330	Diagnostic sigmoidoscopy	45330	Diagnostic sigmoidoscopy.
45331	Sigmoidoscopy and biopsy	45331	Sigmoidoscopy and biopsy.
45332	Sigmoidoscopy w/fb removal	45332	Sigmoidoscopy w/fb removal.
45333	Sigmoidoscopy & polypectomy	45333	Sigmoidoscopy & polypectomy.
45334	Sigmoidoscopy for bleeding	45334	Sigmoidoscopy for bleeding.
45335	Sigmoidoscopy w/submuc inj	45335	Sigmoidoscopy w/submuc inj.
45337	Sigmoidoscopy & decompress	45337	Sigmoidoscopy & decompress.
45338	Sigmoidoscopy w/tumr remove	45338	Sigmoidoscopy w/tumr remove.
45340	Sig w/tndsc balloon dilation	45340	Sig w/tndsc balloon dilation.
45341	Sigmoidoscopy w/ultrasound	45341	Sigmoidoscopy w/ultrasound.
45342	Sigmoidoscopy w/us guide bx	45342	Sigmoidoscopy w/us guide bx.
45346	Sigmoidoscopy w/ablation	45339	Sigmoidoscopy w/ablate tumr.
45347	Sigmoidoscopy w/plcmt stent	45345	Sigmoidoscopy w/stent.
45349	Sigmoidoscopy w/resection	45338	Sigmoidoscopy w/tumr remove.
45350	Sgmdsc w/band ligation	45334	Sigmoidoscopy for bleeding.
45378	Diagnostic colonoscopy	45378	Diagnostic colonoscopy.
45379	Colonoscopy w/fb removal	45379	Colonoscopy w/fb removal.
45380	Colonoscopy and biopsy	45380	Colonoscopy and biopsy.
45381	Colonoscopy submucous njx	45381	Colonoscopy submucous njx.
45382	Colonoscopy w/control bleed	45382	Colonoscopy w/control bleed.
45384	Colonoscopy w/lesion removal	45384	Colonoscopy w/lesion removal.
45385	Colonoscopy w/lesion removal	45385	Colonoscopy w/lesion removal.
45386	Colonoscopy w/balloon dilat	45386	Colonoscopy w/balloon dilat.
45388	Colonoscopy w/ablation	45383	Lesion removal colonoscopy.
45389	Colonoscopy w/stent plcmt	45387	Colonoscopy w/stent.
45390	Colonoscopy w/resection	45385	Colonoscopy w/lesion removal.
45391	Colonoscopy w/endoscope us	45391	Colonoscopy w/endoscope us.
45392	Colonoscopy w/endoscopic fnb	45392	Colonoscopy w/endoscopic fnb.
45393	Colonoscopy w/decompression	45382	Colonoscopy w/control bleed.
45398	Colonoscopy w/band ligation	45382	Colonoscopy w/control bleed.
46500	Injection into hemorrhoid(s)	46500	Injection into hemorrhoid(s).
47135	Transplantation of liver	47135	Transplantation of liver.
5039A	Njx px nfrosgrm &/urtrgrm	50390	Drainage of kidney lesion.
5039B	Njx px nfrosgrm &/urtrgrm	50394	Injection for kidney x-ray.
5039C	Plmt nephrostomy catheter	50392	Insert kidney drain.
5039D	Plmt nephroureteral catheter	50393	Insert ureteral tube.
5039M	Convert nephrostomy catheter	50393	Insert ureteral tube.
5039E	Exchange nephrostomy cath	50398	Change kidney tube.
5069G	Plmt ureteral stent prq	50398	Change kidney tube.
5069H	Plmt ureteral stent prq	50393	Insert ureteral tube.
5069I	Plmt ureteral stent prq	50393	Insert ureteral tube.
5443A	Repair corporeal tear	54406	Remove muti-comp penis pros.
5443B	Replantation of penis	53448	Remov/replc ur sphinctr comp.
657XG	Impltj ntrstrml crnl rng seg	65426	Removal of eye lesion.
7208A	X-ray exam entire spi 1 vw	72050	X-ray exam neck spine 4/5vws.
7208B	X-ray exam entire spi 2/3 vw	72052	X-ray exam neck spine 6/>vws.
7208C	X-ray exam entire spi 4/5 vw	72052	X-ray exam neck spine 6/> vws.
7208D	X-ray exam entire spi 6/> vw	72052	X-ray exam neck spine 6/> vws.
73560	X-ray exam of knee 1 or 2	73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3	73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more	73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees	73565	X-ray exam of knees.
73590	X-ray exam of lower leg	73590	X-ray exam of lower leg.
73600	X-ray exam of ankle	73600	X-ray exam of ankle.
77402	Radiation treatment delivery	G6003	Radiation treatment delivery.
77407	Radiation treatment delivery	G6007	Radiation treatment delivery.
77412	Radiation treatment delivery	G6011	Radiation treatment delivery.
77385	Ntsty modul rad tx dlvr smpl	G6015	Radiation tx delivery imrt.

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES MALPRACTICE RVUS—Continued

77386	Ntsty modul rad tx dlvr cplx	G6015	Radiation treatment delivery.
77387	Guidance for radiaj tx dlvr	77014	Ct scan for therapy guide.
76948	Echo guide ova aspiration	76948	Echo guide ova aspiration.
7778A	Hdr rdncl skn surf brachytx	77785	Hdr brachytx 1 channel.
7778B	Hdr rdncl skn surf brachytx	77786	Hdr brachytx 2–12 channel.
7778C	Hdr rdncl ntrstl/icav brchtx	77785	Hdr brachytx 1 channel.
7778D	Hdr rdncl ntrstl/icav brchtx	77786	Hdr brachytx 2–12 channel.
7778E	Hdr rdncl ntrstl/icav brchtx	77787	Hdr brachytx over 12 chan.
88346	Immunofluorescent study	88346	Immunofluorescent study.
8835X	Immunofluor antb addl stain	88346	Immunofluorescent study.
88367	Insitu hybridization auto	88367	Insitu hybridization auto.
88368	Insitu hybridization manual	88368	Insitu hybridization manual.
91200	Liver elastography	91200	Liver elastography.
9254A	Caloric vestibular test with recording	92540	Basic vestibular evaluation.
9254B	Caloric vestibular test with recording	92540	Basic vestibular evaluation.
99497	Advncd care plan 30 min	99214	Office/outpatient visit est.
99498	Advncd care plan addl 30 min	99214	Office/outpatient visit est.

Note: For any codes not included in Table 14, we are proposing to use the utilization crosswalk, when a crosswalk exists, in order to calculate the malpractice risk factor for these services, as discussed in the preamble text.

a. Lower GI Endoscopy Services

CPT revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that this code set did not allow for accurate reporting of services based upon current medical practice. The RUC subsequently provided recommendations to us for valuing these services. In the CY 2015 PFS final rule with comment period, we delayed valuing the lower GI codes and indicated that we would propose values for these codes in the CY 2016 proposed rule, citing the new process for including proposed values for new, revised and potentially misvalued codes in the proposed rule as one of the reasons for the delay.

(1) Gastrointestinal (GI) Endoscopy (CPT Codes 43775, 44380–46607 and HCPCS Codes G0104, G0105, and G0121)

In the CY 2014 PFS final rule with comment period, we indicated that we used what we called an ''incremental difference methodology'' in valuing the upper GI codes for that year. We explained that the RUC made extensive use of a methodology that uses the incremental difference in codes to determine values for many of these services. This methodology uses a base code or other comparable code and considers what the difference should be between that code and another code by comparing the differentials to those for other sets of similar codes. As with the esophagoscopy subfamily, many of the procedures described within the colonoscopy subfamily have identical counterparts in the esophagogastroduodenoscopy (EGD) subfamily. For instance, the base colonoscopy CPT code 45378 is described as ''Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed, (separate procedure).'' The base EGD CPT code 43235 is described as ''Esophagogastroduodenoscopy, flexible, transoral; diagnostic, with collection of specimen(s) by brushing or washing, when performed.'' In valuing other codes within both subfamilies, the RUC frequently used the difference between these two base codes as an increment for measuring the difference in work involved in doing a similar procedure utilizing colonoscopy versus utilizing EGD. For example, the EGD CPT code 43239 includes a biopsy in addition to the base diagnostic EGD CPT code 43235. The RUC valued this by adding the incremental difference in the base colonoscopy code over the base EGD CPT code to the value it recommended for the esophagoscopy biopsy, CPT code 43202. With some variations, the RUC used this incremental difference methodology extensively in valuing subfamilies of codes. We have made use of similar methodologies in establishing work RVUs for codes in this family.

We agreed with several of the RUC recommendations for codes in this family. Where we did not agree, we consistently applied the incremental difference methodology. Table I7 reflects how we applied this methodology and the values we are proposing. To calculate the base RVU for the colonoscopy subfamily, we looked at the current intraservice time for CPT code 45378, which is 30 minutes, and the current work RVU, which is 3.69. The RUC recommended an intraservice time of 25 minutes and 3.36 RVUs. We then compared that service to the base EGD CPT code 43235 for which the RUC recommended a work RVU of 2.26, giving an increment between EGD and colonoscopy of 1.10 RVUs. We added that increment to our proposed work RVU for CPT 43235 of 2.19 to arrive at our proposed work RVU for the base colonoscopy CPT code 45378 of 3.29. We use this value as the base code in the incremental methodology for establishing the work value for the other base codes in the colonoscopy subfamilies which were then used to value the other codes in that subfamily.

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.05	0.97	Colonoscopy	3.29	Colonoscopy to Ileoscopy.	−2.39	0.9

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
44382	Ileoscopy, through stoma; with biopsy, single or multiple.	1.27	1.27	Ileoscopy	0.9	Biopsy	0.3	1.2
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	NA	3.11	Ileoscopy	0.9	Stent	1.98	2.88
44385	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.82	1.3	Colonoscopy	3.29	Colonoscopy to endo. eval.	−2.06	1.23
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple.	2.12	1.6	Endo. Eval.	1.23	Biopsy	0.3	1.53
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	2.82	2.82	Colonoscopy	3.29	Colonoscopy to Colonoscopy through stoma.	−0.54	2.75
44389	Colonoscopy through stoma; with biopsy, single or multiple.	3.13	3.12	Colonoscopy through stoma.	2.75	Biopsy	0.3	3.05
44390	Colonoscopy through stoma; with removal of foreign body.	3.82	3.82	Colonoscopy through stoma.	2.75	Foreign body	1.02	3.77
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guidewire passage, when performed).	4.7	4.96	Colonoscopy through stoma.	2.75	Stent	1.98	4.73
44403	Colonoscopy through stoma; with endoscopic mucosal resection.	NA	5.81	Colonoscopy through stoma.	2.75	Endoscopic mucosal resection.	2.78	5.53
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	NA	3.13	Colonoscopy through stoma.	2.75	Submucosal injection	0.3	3.05
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed.	0.96	0.84	Colonoscopy	3.29	Colonoscopy to Sigmoidoscopy.	−2.52	0.77
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple.	1.15	1.14	Sigmoidoscopy	0.77	Biopsy	0.3	1.07
45332	Sigmoidoscopy, flexible; with removal of foreign body.	1.79	1.85	Sigmoidoscopy	0.77	Foreign body	1.02	1.79
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.15	Sigmoidoscopy	0.77	Submucosal injection	0.3	1.07
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination.	2.6	2.43	Sigmoidoscopy	0.77	Endoscopic ultrasound ..	1.38	2.15

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	NA	2.97	Sigmoidoscopy	0.77	Ablation	2.07	2.84
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	NA	2.98	Sigmoidoscopy	0.77	Stent	1.98	2.75
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection.	NA	3.83	Sigmoidoscopy	0.77	Endoscopic mucosal resection.	2.78	3.55
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure).	3.69	3.36	Colonoscopy	3.29			
45379	Colonoscopy, flexible; with removal of foreign body.	4.68	4.37	Colonoscopy	3.29	Foreign body	1.02	4.31
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.	4.43	3.66	Colonoscopy	3.29	Biopsy	0.3	3.59
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance.	4.19	3.67	Colonoscopy	3.29	Submucosal injection	0.3	3.59
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	NA	5.5	Colonoscopy	3.29	Stent	1.98	5.27
45390	Colonoscopy, flexible; with endoscopic mucosal resection.	NA	6.35	Colonoscopy	3.29	Endoscopic mucosal resection.	2.78	6.07
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures.	5.09	4.95	Colonoscopy	3.29	Endoscopic ultrasound ..	1.38	4.67

(2) Laparoscopic Sleeve Gastrectomy (CPT Code 43775)

Prior to CY 2013, CPT code 43775 described a non-covered service. For CY 2013, this service was covered as part of the bariatric surgery National Coverage Determination (NCD) and has been contractor-priced since 2013. We are now proposing to establish national pricing for CPT code 43775. To establish a work RVU, we are crosswalking this code to CPT code 37217 (Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation), due to their identical intraservice times, similar total times, and similar levels of intensity. Therefore, we are proposing a work RVU of 20.38 for CPT code 43775.

(3) Incomplete Colonoscopy (CPT codes 44388, 45378, G0105, and G0121)

Prior to CY 2015, according to CPT instruction, an incomplete colonoscopy was defined as a colonoscopy that did not evaluate the colon past the splenic flexure (the distal third of the colon). In accordance with that definition, the Medicare Claims Processing Manual (pub. 100–04, chapter 12, section 30.1.B., available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items*) states that physicians should report an incomplete colonoscopy with 45378 and append modifier -53, which is paid at the same rate as a sigmoidoscopy.

In CY 2015, the CPT instruction changed the definition of an incomplete colonoscopy to a colonoscopy that does not evaluate the entire colon. The 2015 CPT Manual states, ''When performing a diagnostic or screening endoscopic procedure on a patient who is scheduled and prepared for a total colonoscopy, if the physician is unable to advance the colonoscope to the

cecum or colon-small intestine anastomosis due to unforeseen circumstances, report 45378 (colonoscopy) or 44388 (colonoscopy through stoma) with modifier -53 and provide appropriate documentation.''

Given that the new definition of an incomplete colonoscopy also includes colonoscopies where the colonoscope is advanced past the splenic flexure but not to the cecum, we are proposing to establish new values for the incomplete colonoscopies, reported with the -53 modifier. At present, we crosswalk the RVUs for the incomplete colonoscopies from the values of the corresponding sigmoidoscopy. Given that the new CPT instructions will reduce the number of reported complete colonoscopies and increase the number of colonoscopies that proceeded further toward completion reported with the -53 modifier, we believe CPT code 45378 reported with the -53 modifier will now describe a more resource-intensive group of services than were previously reported. Therefore, we are proposing to develop RVUs for these codes reported with the -53 modifier by using one-half the value of the inputs for the corresponding codes reported without the -53 modifier.

In addition to this proposed change in input values, we are also seeking comment on how to address the disparity of resource costs among the broader range of services now described by the colonoscopy codes billed with the -53 modifier. We believe that it may be appropriate for practitioners to report the sigmoidoscopy CPT code 45330 under circumstances when a beneficiary is scheduled and prepared for a total colonoscopy (diagnostic colonoscopy, screening colonoscopy or colonoscopy through stoma), but the practitioner is unable to advance the colonoscope beyond the splenic flexure. We are seeking comment and recommendations on that possibility, as well as more generally, the typical resource costs of these incomplete colonoscopy services under CPT's new definition. Finally, we are seeking information regarding the number of colonoscopies that will be considered incomplete under CPT's new definition relative to the old definition, as well as the number of incomplete colonoscopies where the practitioner is unable to advance the colonoscope beyond the splenicflexure. This information will help us determine whether or not differential payment is required, and if it is, how to make the appropriate utilization assumptions within our ratesetting process.

(4) Malpractice (MP) Crosswalk

We examined the RUC's recommended MP crosswalk for this family of codes. The MP crosswalks are used to identify the presumed mix of specialties that furnish particular services until there is Medicare claims data for the new codes. We direct the reader to section II.B.1. of this proposed rule for further explanation regarding these crosswalks. In reviewing the recommended MP crosswalks for CPT codes 43775, 44407, 44408, 46601, and 46607, we noted that the RUC-recommended MP crosswalk codes are inconsistent with our analysis of the specialties likely to furnish the service based on the description of the services and our review of the RUC-recommended utilization crosswalk. The inconsistency between the RUC's recommended MP and utilization crosswalks is not altogether unusual. However when there are discrepancies between the MP and utilization crosswalk recommendations, they generally reflect the RUC's expectation that due to changes in coding, there will be a different mix of specialties reporting a new code than might be reflected in the claims data for the code previously used to report that service. This often occurs when the new coding structure for a particular family of services is either more or less specific than the old set of codes. In most of these cases, we could identify a rationale for why the RUC's recommended MP crosswalks for these codes were likely to be more accurate than the RUC's recommended utilization crosswalk. But in the case of these codes, the reason for the discrepancies were neither apparent nor explained as part of the recommendation. Since the specialty mix in the claims data is used to determine the specialty mix for each HCPCS code for the purposes of calculating MP RVUs, and that data will be used to set the MP RVUs once it is available, we believe using a specialty mix derived from the claims data of the predecessor codes is more likely to be accurate than the RUC-recommended MP crosswalk as well as more likely to result in stable MP RVUs for these services over several years. Therefore, until claims data under the new set of codes is available, we are proposing to use the specialty mix of the source code(s) in the RUC-recommended utilization crosswalk in order to calculate the malpractice risk factor for these services instead of the RUC-recommended MP crosswalk. Once claims data are available, those data will be incorporated into the calculation of MP RVUs for these services under the MP RVU methodology.

b. Radiation Treatment and Related Image Guidance Services

For CY 2015, the CPT Editorial Panel revised the set of codes that describe radiation treatment delivery services based in part on the CMS identification of these services as potentially misvalued in CY 2012. We identified these codes as potentially misvalued under a screen called ''Services with Stand-Alone PE Procedure Time.'' We proposed this screen following our discovery of significant discrepancies between the RUC-recommended 60 minute procedure time assumptions for intensity modulated radiation therapy (IMRT) and information available to the public suggesting that the procedure typically took between 5 and 30 minutes per treatment.

The CPT Editorial Panel's revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. Four treatment delivery codes (77402, 77403, 77404, and 77406) were condensed into 77402 (Radiation Treatment Delivery, Simple), three treatment delivery codes (77407, 77408, 77409) were condensed into 77407 (Radiation treatment delivery, intermediate), and four treatment codes (77412, 77413, 77414, 77416) were condensed into 77412 (Radiation treatment delivery, complex). Intensity Modulated Radiation Therapy (IMRT) treatment delivery, previously reported under a single code, was split into two codes, 77385 (IMRT treatment delivery, simple) and 77386 (IMRT treatment delivery, complex). The CPT Editorial Panel also created a new image guidance code, 77387 (Guidance for localization of target volume for delivery of treatment, includes intrafraction tracking when performed) to replace 77014 (computed tomography guidance for placement of radiation therapy fields), 77421 (stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy,) and 76950 (ultrasonic guidance for placement of radiation therapy fields) when any of these services were furnished in conjunction with radiation treatment delivery.

In response to stakeholder concerns regarding the magnitude of the coding changes and in light of the process changes we adopted for valuing new and revised codes, we did not implement interim final values for the new codes and delayed implementing the new code set until 2016. To address the valuation of the new code set through proposed rulemaking, and

continue making payment based the previous valuations even though CPT deleted the prior radiation treatment delivery codes for CY 2015, we created G-codes that mimic the predecessor CPT codes (79 FR 67667).

We propose to establish values for the new codes based on RUC recommendations, subject to standard CMS refinements that appear in Table 15 in section II.B.4. of this proposed rule. We also note that because the invoices used to price the capital equipment included ''on-board imaging,'' the cost of that equipment is already reflected in the price per minute associated with the capital equipment. Therefore, we have not included it as a separate item in the proposed direct PE inputs for these codes, even though it appeared as a separate item on the PE worksheet included with the RUC recommendations for these codes. The direct PE inputs for these codes are reflected in the proposed direct PE input database available on the CMS Web site under the supporting data files for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. The RVUs that result from the use of these proposed direct PE inputs (and work RVUs and work time, as applicable) are displayed in Addendum B on the CMS Web site.

In addition to the refinements addressed above, there are three additional issues for which we are seeking comment and/or making specific proposals related to these services: image guidance, equipment utilization rate assumptions for linear accelerators, and superficial radiation treatment services.

(1) Image Guidance Services

Under the previous CPT coding structure, image guidance was separately billable when furnished in conjunction with the radiation treatment delivery services. The image guidance was reported using different CPT codes, depending on which image guidance modality was used. These codes were split into professional and/or technical components that allowed practitioners to report a single component or the global service. The professional component of each of these codes included the work of the physician furnishing the image guidance. CPT code 77014, used to report CT guidance, had a work RVU of 0.85; CPT code 77421, used to report stereotactic guidance, had a work RVU of 0.39, and CPT code 76950, used to report ultrasonic guidance, had a work RVU of 0.58. The technical component of these codes incorporated the resource costs of the image guidance capital equipment (such as CT, ultrasound, or stereotactic) and the clinical staff involved in furnishing the image guidance associated with the radiation treatment. When billed globally, the RVUs reflected the sum of the professional and technical components. In the revised coding structure, one new image guidance code is to be reported regardless of the modality used, and in developing its recommended values, the RUC assumed that CT guidance would be typical.

However, the 2013 Medicare claims data for separately reported image guidance indicates that stereotactic guidance for radiation treatment services was furnished more frequently than CT guidance. The RUC has recommended a work RVU of 0.58 and associated work times of 3 pre-service minutes, 10 intraservice minutes, and 3 post-service minutes for image guidance CPT code 77387. We reviewed this recommendation considering the discrepancy between the modality the RUC assumed to be typical in the vignette and the modality typically reported in the Medicare claims data. Given that the recommended work RVU for the new single code is similar to the work RVUs of the predecessor codes, roughly prorated based on their distribution in Medicare claims data, we agree with the RUC-recommended work RVU for the service. However, the RUC also recommended an increase in overall work time associated with image guidance consistent with the survey data used to value the new services. If accurate, this increase in time and maintenance of total work would suggest a decrease in the overall intensity for image guidance relative to the current codes. Given this implication, we are seeking comment as to the appropriate work time associated with CPT code 77387.

Although 77421 (stereotactic guidance) and 76950 (ultrasonic guidance) have been deleted, we note that CPT maintained CPT code 77014 (Computed tomography guidance for placement of radiation therapy fields) and the RUC recommendation states that CPT did so based on concerns that without this option, some practitioners might have no valid CPT alternative than to use higher valued diagnostic CT codes when they used this CT guidance. The RUC recommendation also includes a statement that utilization of this code is expected to drop to negligible levels by 2015, assuming that practitioners would use the new codes that are not differentiated based on imaging modality. Once all the new codes are implemented for Medicare, we anticipate that CPT and/or the RUC will address the continued use of 77014 and, if it continues to be part of the code set, provide recommendations as to the appropriate values given changes in utilization.

Regarding the reporting of the new image guidance codes, CPT guidance instructs that the technical portion of image guidance is now bundled into the IMRT and Stereotactic Radiation Treatment delivery codes, but it is not bundled into the simple, intermediate, and complex radiation treatment delivery codes. CPT guidance states that the technical component of the image guidance code can be reported with codes 77402, 77407, and 77412 (simple, intermediate, and complex radiation treatment) when furnished, which means that the technical component of the image guidance code should not be reported with the IMRT or Stereotactic Radiation Treatment delivery codes. The RUC recommendation, however, incorporates the same capital cost of image guidance equipment (a linear accelerator, or linac), for all these radiation treatment delivery codes, including the codes that describe IMRT and Stereotactic Radiation Treatment delivery services. The RUC explains that the recommendations were done this way because the older lower-dose external beam radiation machines are no longer manufactured and the image guidance technology is integrated into the single kind of linear accelerator used for all the radiation treatment services. In reviewing the new code structure and the RUC recommendations, we assume that the CPT editorial panel did not foresee that the RUC would recommend that we develop PE RVUs for all the radiation treatment delivery codes based on the assumption that the same capital equipment is typically used in furnishing the entire range of external beam radiation treatments. Because the RUC recommendations incorporate the more extensive capital equipment in the lower dose treatment codes as well, a portion of the resource costs of the technical portion of imaging guidance are already allocated into the PE RVUs for all of the treatment delivery codes, not just the IMRT and Stereotactic Radiation Treatment delivery codes as CPT guidance would suggest.

In order to avoid incorporating the cost of this equipment into both the treatment delivery codes (77402, 77407, and 77412) and the technical component of the new imaging guidance code (77387–TC), we considered valuing 77387 as a professional service only and not creating the professional/technical component splits envisioned by CPT. In the context of the budget neutral PFS, incorporating a duplicative

direct input with a cost of more than six dollars per minute has significant impacts on the PE RVUs for all other services. However, we also noted that the RUC did not address this apparent contradiction in its recommendation and not all of the recommended direct PE inputs for the technical component of 77387 are capital equipment costs. Therefore, we are proposing to allow for professional and technical component billing for these services, as reflected in CPT guidance, and we are proposing to use the RUC recommended direct PE inputs for these services (refined as described in Table 15). However, we are also seeking comment on the apparent contradiction between technical component billing for image guidance in the context of the inclusion of a single linac with integrated imaging guidance technology being included for all external beam treatment codes.

(2) Equipment Utilization Rate for Linear Accelerators

The cost of the capital equipment is the primary determining factor in the payment rates for these services. For each CPT code, the equipment costs are estimated based on multiplying the assumed number of minutes the equipment is used for that procedure by the per minute cost of the particular equipment item. Under our PE methodology, we currently use two default equipment usage assumptions in allocating capital equipment costs to calculate PE RVUs. The first is that each equipment item is only available to be used during what are assumed to be regular business hours for a physician's office: 10 hours per day, 5 days per week (50 hours per week) and 50 weeks per year. The second assumption is that the equipment is in use only 50 percent of the time that it is available for use. The current default 50 percent utilization rate assumption translates into 25 hours per week out of a 50-hour work week.

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 justify 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.

Subsequently, a 2009 report on equipment utilization by MedPAC included studies that suggested a higher utilization rate for diagnostic imaging equipment costing more than $1 million. These studies cited by MedPAC suggested that for Magnetic Resonance Imaging equipment, a utilization rate of 92 percent on a 50-hour week would be most accurate. Similarly, another MedPAC cited study suggested that for Computed Tomography scanners, 45 hours was more accurate and that is equivalent to a 90 percent utilization rate on a 50-hour work week. For the CY 2010 PFS proposed rule, we proposed to increase the equipment usage rate to 90 percent for all services containing equipment that cost in excess of $1 million dollars. We stated that the studies cited by MedPAC suggested that physicians and suppliers would not typically make huge capital investments in equipment that would only be utilized 50 percent of the time (74 FR 33532).

In response to comments to that proposal, we finalized a 90 percent utilization rate assumption for MRI and CT to be transitioned over a 4-year period. Regarding the utilization assumptions for other equipment priced over $1 million, we stated that we would continue to explore data sources regarding use of the most accurate utilization rates possible (74 FR 61755). Congress subsequently specified the utilization rate to be assumed for MRI and CT by successive amendments to Section 1848(b)(4)(C) of the Act. Section 3135(a) of the Affordable Care Act (Pub. L. 111–148) set the assumed utilization rate for expensive diagnostic imaging equipment to 75 percent, effective for 2011 and subsequent years. Section 635 of the American Taxpayer Relief Act (ATRA) (Pub. L. 112–240) set the assumed equipment utilization rate to 90%, effective for 2014 and subsequent years. Both of these changes were exempted from the budget neutrality requirements described in section 1848(c)(2)(B)(ii)(II) of the Act.

We have also made other adjustments to the default assumptions regarding the number of hours for which the equipment is available to be used. For example, some equipment used in furnishing services to Medicare beneficiaries is available to be used on a 24-hour/day, 7 days/per week basis. For these items, we develop the rate per minute by amortizing the cost over the extended period of time the equipment is in use.

Based on the RUC recommendations for the new codes that describe radiation treatment services, we do not believe our default assumptions regarding equipment usage are accurate for the capital equipment used in radiation treatment services. As we noted above, the RUC recommendations assume that the same type of linear accelerator is now typically used to furnish all levels and types of external beam radiation treatment services because the machines previously used to furnish these services are no longer manufactured. In valuing the previous code set and making procedure time assumptions, different equipment items were assumed to be used to furnish the different levels and types of radiation treatment. With the current RUC-recommended inputs, we can then assume that the same equipment item is used to furnish more services. If we assume the RUC recommendation to include the same kind of capital equipment for all of these codes is accurate, we believe that it is illogical to continue to assume that the equipment is only used for 25 out of a possible 50 hours per week. In order to estimate the difference between the previous number of minutes the linear accelerator was assumed to be in use under the previous valuation and the number of minutes now being recommended, we applied the change in assumptions to the services reported in the most recent year of Medicare claims data. Under the assumptions reflected in the previous direct PE inputs, the kind of linear accelerator used for IMRT made up a total of 44.8 million out of 65 million minutes of external beam treatments furnished to Medicare beneficiaries. Under the new code set, however, a single kind of linear accelerator would be used for all of the 65 million minutes furnished to Medicare beneficiaries. This represents a 45 percent increase in the aggregate amount of time that this kind of linac is in use. Of course, the utilization rate that corresponds with that increase in minutes is not necessarily precise since the current utilization rate only reflects the default assumption and is not itself rooted in empirical data. Additionally, in some cases, individual practices that already use linear accelerators for IMRT may have replaced the now-obsolete capital equipment with new, additional linear accelerators instead of increasing the use of capital equipment already owned. However, we do not believe that the latter scenario is likely to be common in cases where the linear accelerators had previously been used only 25 hours per week.

Therefore, we are proposing to adjust the equipment utilization rate

assumption for the linear accelerator to account for the significant increase in usage. Instead of applying our default 50 percent assumption, we are proposing to use a 70 percent assumption based on the recognition that the item is now being typically used in a significantly broader range of services, and that would increase its overall usage in comparison to the previous assumption. We note that we developed the 70 percent rate based on a rough reconciliation between the number of minutes the equipment is being used according to the new recommendations versus the current number of minutes based on an analysis of claims data. We continue to seek evidence to ensure that the usage assumptions, both the utilization rate and number of available hours, used to calculate equipment costs are as accurate as possible. We believe that comparing the changes in direct PE input recommendations and using the Medicare claims data indicates that the utilization assumption to 70 percent is more accurate than the default utilization assumption of 50 percent. However, we have reviewed other information that suggests this utilization rate may be higher than 70 percent and that the number of available hours per week is greater than 50.

For example, as part of the 2014 RUC recommendations for the Radiation Treatment Delivery codes, the RUC submitted a 2011 staffing survey conducted by the American Society for Radiology Technicians (ASRT). Using the 2014 version of the same study, we noted that there are an average of 2.3 linacs per radiation treatment facility and 52.7 patients per day treated per radiation treatment facility. These data suggest that an average of 22.9 patients is treated on each linac per day. Using an average of the RUC-recommended procedure times for CPT codes 77385, 77386, 77402, 77407, and 77412 weighted by the annual volume of procedures derived from Medicare claims data yielded a total of 670.39 minutes or 11.2 hours that a single linac is in use per day. This is in contrast to both the number of hours of use reflected in our default assumptions (5 of the 10 available business hours per day) and in our proposed revision to the equipment utilization rate assumption (7 hours out of 10 available business hours per day).

For advanced diagnostic imaging services, we finalized a policy to change the equipment utilization assumption only by 10 percent per year, in response to suggestions from commenters. Because capital equipment costs are amortized over several years, we believe it is reasonable to transition changes to the default assumptions for particular items over several years. We note that the change from one kind of capital equipment to another is likely to occur over a number of years, roughly equivalent to the useful life of particular items as they become obsolete. In the case of most of these items, we have assumed a 7-year useful life, and therefore, we assume that the transition to use of the single kind of capital equipment would likely take place over 7 years as individual pieces of equipment age into obsolescence. However, in the case of this transition in capital equipment, we have reasons to believe that the transition to the new capital equipment has already occurred. First, we note that the specialty societies concluded that the single linear accelerator was typical for these services at the time that the current recommendations were developed in 2013. Therefore, we believe it is logical to assume that, at a minimum, the first several years of the transition to new capital equipment had already taken place by 2013. This would account for the linear accelerator being typically used at that time. This would not be surprising, given that prior to the 2013 review by the RUC, the codes describing the non-IMRT external beam radiation treatments had last been reviewed in 2002. Second, because we are proposing to use the 2013 recommendations for 2016 PFS payment rates, we believe it would be reasonable to assume that in the years between 2013 and 2016, the majority of the rest of the obsolete machines would have been replaced with the single linear accelerator.

Nonetheless, we recognize that there would be value in following precedent to transition changes in utilization assumptions over several years.

Given the fact that it is likely that the transition to the linear accelerator began prior to the 2013 revaluation of the radiation treatment delivery codes by CPT and that the useful life of the newest generation of linear accelerator is 7 years, we believe a 2-year transition to the 70 percent utilization rate assumption would account for any remaining time to transition to the new equipment. Therefore, in developing PE RVUs for these services, we are proposing to use a 60 percent utilization rate assumption for CY 2016 and a 70 percent utilization rate assumption for CY 2017. The PE RVUs displayed in addendum B on the CMS Web site were calculated using the proposed 60 percent equipment utilization rate for the linac as displayed in the CY 2016 direct PE input database.

Additionally, we continue to seek empirical data on the capital equipment costs, including equipment utilization rates, for the linac and other capital-intensive machines, and seek comment on how to most accurately address issues surrounding those costs within the PE methodology.

(3) Superficial Radiation Treatment Delivery

In the CY 2015 PFS final rule with comment period, we noted that changes to the CPT prefatory language modify the services that are appropriately billed with CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other procedures supporting superficial radiation therapy were bundled with 77401. The RUC, however, did not review the inputs for superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. Some stakeholders suggested that the change in the prefatory language precluded them from billing for codes that were previously frequently billed in addition to this code and expressed concern that as a result there would be significant reduction in their overall payments. In the CY 2015 PFS final rule with comment period, we requested information on whether the new radiation therapy code set combined with modifications in prefatory text allowed for appropriate reporting of the services associated with superficial radiation and whether the payment continued to reflect the relative resources required to furnish superficial radiation therapy services.

In response to our request, we received a recommendation from a stakeholder to make adjustments to both the physician work and PE components for code 77401. The stakeholder suggested that since crucial aspects of the service, such as treatment planning and device design and construction, were not currently reflected in 77401, and practitioners were precluded from reporting these activities separately, that physician work should be included for CPT code 77401. Additionally, the stakeholders suggested that the current inputs used to value the code are not accurate because the inputs include zero physician work and minutes for a radiation therapist to provide the service directly to the patient. The stakeholders suggested, alternatively, that physicians, not radiation therapists, typically provide superficial radiation services directly. Therefore, we are seeking recommendations from other stakeholders, including the RUC, regarding whether or not it would be

appropriate to add physician work for this service and remove minutes for the radiation therapists, even though physician work is not included in other radiation treatment services.

The stakeholder also suggested that we amend the direct PE inputs by including nurse time and updating the price of the capital equipment used in furnishing the service. We believe it would be most appropriate to address the clinical labor assigned to the code in the context of the information regarding the physician work that might be associated with the service. Therefore, we seek information on the possible inclusion of nurse time for this service as part of the comments and/or recommendations regarding physician work for the service. However, we reviewed the submitted invoices for the request to update the capital equipment for the service. We are proposing to update the equipment item ER045 ''orthovoltage radiotherapy system'' by renaming it ''SRT–100 superficial radiation therapy system'' and updating the price from $140,000 to $216,000, on the basis of the submitted invoices. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with this proposed modification that is displayed in the CY 2016 direct PE input database.

c. Advance Care Planning Services

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning (ACP) services: CPT code 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 professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate); and an add-on CPT code 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 professional; each additional 30 minutes (List separately in addition to code for primary procedure)). In the CY 2015 PFS final rule with comment period (79 FR 67670–71), we assigned a PFS interim final status indicator of ''I'' (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services) to CPT codes 99497 and 99498 for CY 2015. We said that we would consider whether to pay for CPT codes 99497 and 99498 after we had the opportunity to go through notice and comment rulemaking.

We received many public comments to the final rule recommending that we recognize these two CPT codes and make separate payment for ACP services, in view of the time required to furnish the services and their importance for the quality of care and treatment of the patient. For CY 2016, we are proposing to assign CPT codes 99497 and 99498 PFS status indicator ''A,'' which is defined as: ''Active code. These codes are separately payable under the PFS. There will be RVUs for codes with this status.'' The presence of an ''A'' indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. We are proposing to adopt the RUC-recommended values (work RVUs, time, and direct PE inputs) for CPT codes 99497 and 99498 beginning in CY 2016 and will consider all public comments that we receive on this proposal.

Physicians' services are covered and paid by Medicare in accordance with section 1862(a)(1)(A) of the Act. Therefore, CPT code 99497 (and CPT code 99498 when applicable) should be reported when the described service is reasonable and necessary for the diagnosis or treatment of illness or injury. For example, this could occur in conjunction with the management or treatment of a patient's current condition, such as a 68 year old male with heart failure and diabetes on multiple medications seen by his physician for the evaluation and management of these two diseases, including adjusting medications as appropriate. In addition to discussing the patient's short-term treatment options, the patient expresses interest in discussing long-term treatment options and planning, such as the possibility of a heart transplant if his congestive heart failure worsens and advance care planning including the patient's desire for care and treatment if he suffers a health event that adversely affects his decision-making capacity. In this case the physician would report a standard E/M code for the E/M service and one or both of the ACP codes depending upon the duration of the ACP service. However, the ACP service as described in this example would not necessarily have to occur on the same day as the E/M service.

We seek comment on this proposal, including whether payment is needed and what type of incentives this proposal creates. In addition, we seek comment on whether payment for advance care planning is appropriate in other circumstances such as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act.

d. Proposed Valuation of Other Codes for CY 2016

(1) Excision of Nail Bed (CPT Code 11750)

The RUC's review of 10-day global services identified 18 services currently valued with greater than 1.5 office visits and 2012 Medicare utilization data over 1,000, including CPT code 11750. As a result, the RUC requested this service be surveyed for work and reviewed for CY 2016.

The RUC recommended a work RVU of 1.99 for CPT code 11750, despite a decrease in the associated post-operative visits. We believe the recommendation for this service overstates the work involved in performing this procedure specifically given the decrease in post-operative visits. Due to similarity in service and time, we believe a direct crosswalk of the work RVUs for CPT code 10140 (Drainage of blood or fluid accumulation), which is also a 10 day global service with one post-operative visit, to CPT code 11750 more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2016 we are proposing a work RVU of 1.58 for CPT code 11750.

(2) Bone Biopsy Excisional (CPT Code 20240)

In the same review of 10-day global services, the RUC identified CPT code 20240 as potentially misvalued. As a result, the RUC requested this service be surveyed and reviewed for CY 2016. Subsequent to this identification, the RUC also requested and we approved a global period change from a 10-day to a 0-day global period for this procedure. Based on the survey data, the RUC recommended a decrease in the intraservice time from 39 to 30 minutes, removal of two postoperative visits (one 99238 and one 99212), and an increase in the work RVUs for CPT code 20240 from 3.28 to 3.73. We do not believe this recommendation accurately reflects the work involved in this procedure, especially given the decrease in intraservice time and post-operative visits. Therefore, for CY 2016, we are proposing a work RVU of 2.61 for CPT code 20240 based on the reductions in time for the service.

(3) Endobronchial Ultrasound (CPT Codes 31622, 3160A, 3160B, 31625, 31626, 31628, 31629, 3160C, 31632 and 31633)

For CY 2016, the CPT Editorial Panel deleted one code, CPT 31620 (Ultrasound of lung airways using an endoscope), and created three new codes, CPT 3160A–3160C, to describe bronchoscopic procedures that are inherently performed with endobronchial ultrasound (EBUS).

In their review of the newly revised EBUS family, the RUC recommended a change in the work RVU for CPT code 31629 from 4.09 to 4.00. The RUC also recommended maintaining the current work RVUs for CPT codes 31622, 31625, 31626, 31628, 31632 and 31633. We are proposing to use those values for CY 2016.

For the newly created codes, the RUC recommended a work RVU of 5.00 for CPT code 3160A, 5.50 for CPT code 3160B and 1.70 for CPT code 3160C. We believe the recommended work RVUs for these services overstate the work involved in furnishing the procedures. In order to develop proposed work RVUs for CPT code 3160A, we compared the service described by the new code to deleted CPT codes 31620 and 31629, because this new code describes a service that combines services described by 31620 and 31629. Specifically, we took the sum of the current work RVU of CPT code 31629 (WRVU=4.09) and the CY 2015 work RVU of CPT code 31620 (WRVU=1.40) and multiplied it by the quotient of CPT code 3160A's RUC-recommended intraservice time (INTRA=60 min) and the sum of CPT codes 31620 and 31629's current and CY 2015 intraservice times (INTRA=70 min), respectively. This resulted in a work RVU of 4.71 and we are proposing that value. To value CPT code 3160B, we used the RUC-recommended increment of 0.5 work RVU between this service and CPT code 3160A to calculate for CPT code 3160B our proposed work RVUs of 5.21. Lastly, because the service described by new CPT code 3160C is very similar to deleted CPT code 31620, we believe a direct crosswalk of the previous values for 31620 accurately reflects the time and intensity of furnishing the service described by 3160C. Therefore, we are proposing a work RVUs of 1.40 for CPT code 3160C.

(4) Laparoscopic Lymphadenectomy (CPT Codes 38570, 38571 and 38572)

The RUC identified three laparoscopic lymphadenectomy codes as potentially misvalued: CPT code 38570 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple); CPT code 38571 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple with bilateral total pelvic lymphadenectomy); and CPT code 38572 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple with bilateral total pelvic lymphadenectomy and periaortic lymph node sampling (biopsy), single or multiple). Accordingly, the specialty society resurveyed these 10-day global codes, and the survey results indicated decreases in intraservice and total work times. After reviewing the survey responses, the RUC recommended that CMS maintain the current work RVU for CPT code 38570 of 9.34; reduce the work RVU for CPT code 38571 from 14.76 to 12.00; and reduce the work RVU for CPT code 38572 from 16.94 to 15.60. We propose to accept the RUC recommendations for CPT codes 38571 and 38572, as the RUC is recommending reductions in the work RVUs that correspond with marked decreases in intraservice time and decreases in total time. However, we do not agree with the RUC's recommendation to maintain the current work RVU for CPT code 38570 in spite of similar changes in intraservice and total times as were shown in the RUC recommendations for CPT codes 38571 and 38572. Therefore, we propose to reduce the work RVU for CPT code 38570 to 8.49, which reflects the ratio of the reduction in total time for this code and would maintain rank order among the three codes.

(5) Mediastinoscopy With Biopsy (CPT Codes 3940A and 3940B)

The RUC identified CPT code 39400 (Mediastinoscopy, including biopsy(ies) when performed) as a potentially misvalued code due to an unusually high preservice time and Medicare utilization over 10,000. In reviewing the code's history, it became apparent that the code has been used to report two distinct procedural variations although the code was valued using a vignette for only one of them. As a result, CPT code 39400 is being deleted and replaced with CPT codes 3940A and 3940B to describe each of the two mediastinoscopy procedures.

We are proposing to accept the RUC-recommended work RVU of 5.44 for code 3940A. We agree with the RUC that the crosswalk from CPT code 52235 (Cystourethroscopy, with fulguration) appropriately estimates the overall work for CPT code 3940A. For CPT code 3940B, we disagree with the RUC recommended work RVU of 7.50. We believe that the work value for CPT code 3940A establishes an accurate baseline for this family of codes, so we are scaling the work RVU of CPT code 3940B in accordance with the change in the intraservice times between CPT codes 3940A and 3940B. Applying this ratio in the intraservice time to the work value of CPT code 3940A yields a total work RVU of 7.25 for CPT code 3940B. We also note that the RUC recommendation for CPT code 3940A represents a decrease in value by 0.64 work RVUs, which is roughly proportionate to the reduction from a full hospital discharge visit (99238) to a half discharge visit assumed to be typical in the post-operative period. The RUC recommendation for CPT code 3940B had the same reduction in the post-operative work without a corresponding decrease in its recommended work RVU. In order to reflect the reduction in post-operative work and to maintain relativity between the two codes in the family, we are proposing 7.25 as the work RVU for CPT code 3940B.

(6) Hemorrhoid(s) Injection (CPT Code 46500)

The RUC also identified CPT code 46500 (Injection of sclerosing solution, hemorrhoids) as potentially misvalued, and the specialty society resurveyed this 10-day global code. The survey showed a significant decrease in the reported intraservice and total work times. After reviewing the survey responses, the RUC recommended that CMS should maintain the current work RVU of 1.69 in spite of these drops in intraservice and total times. We propose to instead reduce the work RVU to 1.42, which reduces the work RVU by the same ratio as the reduction in total time.

We are also proposing to refine the recommended PE inputs by removing the inputs associated with cleaning the scope. As recommended by the RUC, we are proposing to include a scope as a direct PE input that is disposable, and therefore, does not require cleaning.

(7) Liver Allotransplantation (CPT Code 47135)

The RUC also identified CPT code 47135 (Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age) as potentially misvalued, and the specialty society resurveyed this 90-day global code. The survey showed a significant decrease in reported intraservice work time, but a significant increase in total work time (the number of post-operative visits significantly declined while the level of visits increased). After reviewing the survey responses, the

RUC recommended an increase in the work RVU from 83.64 to 91.78, which is the median of the survey, as well as the exact value for CPT code 33935 (Heart-lung transplant with recipient cardiectomy-pneumonectomy). However, we do not believe this crosswalk is the most accurate from among the group of transplant codes. CPT code 32854 (Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) has intraservice and total times that are closer to those the RUC recommended for CPT code 47135, and CPT code 32854 has a work RVU of 90.00 which is the 25th percentile of the survey for CPT code 47135. Therefore, we propose to increase the work RVU of CPT code 47135 to 90.00.

(8) Genitourinary Catheter Procedures (CPT Codes 5039A, 5039B, 5039C, 5039D, 5039M, 5039E, 5069G, 5069H, 5069I)

For CY 2016, the CPT Editorial Panel is deleting six codes (50392, 50393, 50394, 50398, 74475, and 74480) that were commonly reported together, and are creating 12 new codes both to describe these genitourinary catheter procedures more accurately and to bundle inherent imaging services. Three of these codes (506XF, 507XK, and 507XL) were referred back to CPT to be resurveyed as add-on codes. The other nine codes were reviewed at the January 2015 RUC meeting and assigned recommended work RVUs and direct PE inputs.

We are proposing to use the RUC-recommended work RVU of 3.15 for CPT code 5039A. We agree that this is an appropriate value, and that the code should be used as a basis for establishing relativity with the rest of the family. As a result, we began by making comparisons between the service times of CPT code 5039A and the other codes in the family in order to determine the appropriate proposed work value of each procedure.

For CPT code 5039B, we disagree with the RUC recommended work RVU of 1.42, and we are instead proposing a work RVU of 1.10, based on three separate data points. First, the RUC summary of recommendations stated that CPT code 5039B describes work previously described by a combination of CPT codes 50394 and 74425. These two codes have work RVUs of 0.76 and 0.36, respectively, which sum together to 1.12. Second, we noted that the work of CPT code 49460 (Mechanical removal of obstructive material from gastrostomy) is similar, with the same intraservice time of 15 minutes and same total time of 55 minutes but a work RVU of 0.96. Finally, we observed that the minimum survey result had a work RVU of 1.10, and we believe this value appropriately reflects the total work for the service. Accordingly, we are proposing 1.10 as the work RVU for CPT code 5039B.

We employed a similar methodology to develop a proposed work RVU of 4.25 for CPT code 5039C. The three previously established codes are being combined in CPT code 5039C; these had respective work values of 3.37 (CPT code 50392), 0.54 (CPT code 74475), and 0.36 (CPT code 74425); together these sum to 4.27 work RVUs. We also looked at valuing CPT code 5039C based on relativity with other codes in the family. The ratio of the intraservice time of 35 minutes for CPT code 5039A and the intraservice time of 48 minutes for CPT code 5039C; applied to the work RVU of base code 5039A (3.15) results in a potential work RVU of 4.32. The total time compared to CPT code 5039A also went from 91 minutes to 107 minutes and this ratio applied to the base work RVU results in a work RVU of 3.70. We utilized these data to inform our choice of an appropriate crosswalk. We believe CPT code 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance) is an appropriate reference crosswalk for CPT code 5039C. CPT code 31660 has an intraservice time of 50 minutes, total time of 105 minutes, and a work RVU of 4.25. Therefore, we propose to establish the work RVU for CPT code 5039C at the crosswalked value of 4.25 work RVUs.

According to the RUC recommendations, CPT codes 5039C and 5039D are very similar procedures, with CPT code 5039D making use of a nephroureteral catheter instead of a nephrostomy catheter. The RUC valued the added difficulty of CPT code 5039D at 1.05 work RVUs compared to code CPT code 5039C. We are maintaining the relative difference in work between these two codes by proposing a value of 5.30 for CPT code 5039D. (This is the work RVU of 4.25 for CPT code 5039C plus 1.05 RVUs.) Additionally, we are using CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) as our reference crosswalk. CPT code 57155 has a work RVU of 5.40 and an identical intraservice time of 60 minutes, but it also has fourteen additional minutes of total time, 133 minutes compared to 119 minutes for CPT code 5039D, which supports the difference of 0.10 RVUs. For these reasons, we are proposing the value of CPT code 5039D at 5.30 work RVUs.

As with the other genitourinary codes, we developed the proposed work value of CPT code 5039M in order to preserve relativity within the family. CPT code 5039M has 15 fewer minutes of intraservice time compared to CPT code 5039D (45 minutes compared to 60 minutes). This is a ratio of 0.75, applied to the based work RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 3.98. CPT code 5039C was another close match within the family, with 3 more minutes of intraservice time compared to 5039M, 48 minutes of intraservice time instead of 45 minutes. This ratio (0.94) applied to the base work RVU of CPT code 5039C (4.25) also resulted in a potential work RVU of 3.98. Based on this information, we identified CPT code 31634 (Bronchoscopy, rigid or flexible, with balloon occlusion) as an appropriate crosswalk, and propose a work RVU of 4.00 for CPT code 5039M. The two codes share an identical intraservice time of 45 minutes, though the latter possesses a lower total time of 90 minutes.

For CPT code 5039E, we considered how the code and work RVU would fit within the family in comparison to our proposed values for CPT codes 5039A and 5039C. CPT code 5039A serves as the base code for this group; it has 35 minutes of intraservice time in comparison to 20 minutes for CPT code 5039E. This intraservice time ratio of 0.57 resulted in a potential work RVU of 1.80 for CPT code 5039E when applied to the work RVU of CPT code 5039A (3.15). Similarly, CPT code 5039C is the most clinically similar procedure to CPT code 5039E. CPT code 5039C has 48 minutes of intraservice time compared to 20 minutes of intraservice time for CPT code 5039E. This ratio of 0.42 applied to the base work RVU of CPT code 5039C (4.25) results in a potential work RVU of 1.77. We also made use of two crosswalks to help determine a proposed value for CPT code 5039E. CPT code 64416 (Injection, anesthetic agent; brachial plexus) also includes 20 minutes of intraservice time and has a work RVU of 1.81. CPT code 36569 (Insertion of peripherally inserted central venous catheter) has the same intraservice and total time as CPT code 5039E, with a work RVU of 1.82. Accordingly, we are crosswalking the work RVU for CPT code 5039E to CPT code 36569 and proposing a work RVU of 1.82 for CY 2016.

The remaining three codes all utilize ureteral stents and form their own small subfamily within the larger group of genitourinary catheter procedures. For CPT code 5069G, we are proposing a

work RVU of 4.21, which is the 25th percentile result from the survey information. We believe that the 25th percentile provides a more accurate value for CPT code 5069G based on the work involved in the procedure and within the context of other codes in the family. We are also referencing CPT code 31648 (Bronchoscopy, rigid or flexible, with removal of bronchial valve), which shares 45 minutes of intraservice time and has a work RVU of 4.20, as an appropriate crosswalk for CPT code 5069G.

For CPT code 5069H, we compared its intraservice time to the code within the family that had the most similar duration, CPT code 5039D. This code has 60 minutes of intraservice time compared to 62 minutes for CPT code 5069H. This is a ratio of 1.03 applied to the base work RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 5.48. We also looked to crosswalks with similar numbers, in particular CPT code 50382 (Removal and replacement of internally dwelling ureteral stent). This code has 60 minutes of intraservice time, 125 minutes of total time, and a work RVU of 5.50. For these reasons, we are crosswalking CPT code 5069H to CPT code 50382 and proposing a work RVU of 5.50.

Finally, we developed the proposed value for CPT code 5069I using three related methods. CPT codes 5069H and 5069I describe very similar procedures, with 5069I adding the use of a nephrostomy tube. The RUC addressed the additional difficulty of this procedure by recommending 1.55 more work RVUs for CPT code 5069I than for CPT code 5069H. Adding the 1.55 work RVUs to the proposed work RVU for CPT code 5069H (5.50) would produce a work RVU of 7.05 for CPT code 5069I. We also looked at the ratio of intraservice times for CPT code 5069I (75 minutes) and the base code in the subfamily, CPT code 5069G (45 minutes). The intraservice time ratio between these two codes is 1.67 when applied to the base work RVU of CPT code 5069G (4.21) resulted in a potential work RVU of 7.02. We also identified an appropriate crosswalk reference in CPT code 36481 (Percutaneous portal vein catheterization by any method) which shares the same intraservice time as CPT code 5069I and has a work RVU of 6.98. Accordingly, to maintain relativity among this subfamily of codes, we are proposing a work RVU of 7.05 for CPT code 5069I based on an incremental increase of 1.55 RVUs from CPT code 5069H.

In reviewing the direct PE inputs for this family of codes, we refined a series of the RUC- recommended inputs in order to maintain relativity with current standards. All of the following refinements refer to the non-facility setting for this family of codes. Under the clinical labor inputs, we are proposing to remove the RN/LPN/MTA (L037D) (intraservice time for assisting physician in performing procedure) for CPT codes 5039B and 5039E. This amounts to 15 minutes for CPT code 5039B and 20 minutes for CPT code 5039E. Moderate sedation is not inherent in these procedures and, therefore, we do not believe that this clinical labor task would typically be completed in the course of this procedure. We are also reducing the RadTech (L041B) intraservice time for acquiring images from 47 minutes to 46 minutes for CPT code 5069H. This procedure contains 62 minutes of intraservice time, with clinical labor assigned for acquiring images (75 percent) and a circulator (25 percent). The exact time for these clinical labor tasks multiplies out to 46.5 minutes and 15.5 minutes, respectively. The RUC recommendation for CPT code 5069H rounded both of these values upwards, assigning 47 minutes for acquiring images and 16 minutes for the circulator, which together sum to 63 minutes. We are reducing the clinical labor time for acquiring images to 46 minutes to preserve the 62 minutes of total intraservice time for CPT code 5069H.

During the post-service portion of the clinical labor service period, we are proposing to change the labor type for the ''patient monitoring following service/check tubes, monitors, drains (not related to moderate sedation)'' input. There are 45 minutes of clinical labor time assigned under this category to CPT codes 5039A, 5039C, 5039D, 5039M, 5069G, 5069H, and 5069I. Although we agree that the 45 minutes are appropriate for these procedures as part of moderate sedation, we are changing the clinical labor type from the recommended RN (L051A) to RN/LPN/MTA (L037D) to reflect the staff that will typically be doing the monitoring for these procedures. Even though the CPT Editorial Committee's description of post-service work for CPT code 5039E includes a recovery period for sedation, we recognize that according to the recommendation, CPT codes 5039B and 5039E do not use moderate sedation, so we did not propose to include moderate sedation inputs for these codes.

The RUC recommendation for CPT code 5039D includes a nephroureteral catheter as a new supply input with an included invoice. However, in the RUC summary of recommendations for this code, there is no mention of a nephroureteral catheter in the intraservice work description. CPT code 5039D does mention the use of a nephroureteral stent in this description, but there is no request for a nephroureteral stent supply item on the PE worksheet for this code. We are therefore seeking clarification from stakeholders regarding the use of the nephroureteral catheter for CPT code 5039D. We have not proposed to add the nephroureteral catheter as a supply item for CPT code 5039D pending this information. We are also requesting a clarification to the intraservice work description in the summary of recommendations for this code to explain the use, if any, of the nephroureteral catheter in this procedure.

The RUC recommended the inclusion of ''room, angiography'' (EL011) for this family of codes. We do not agree with the RUC that an angiography room would be used in the typical case for these procedures, as there are other rooms available which can provide fluoroscopic guidance. Most of the codes that make use of an angiography room are cardiovascular codes, and much of the equipment listed for this room would not be used for non-cardiovascular procedures. We are therefore proposing to replace equipment item ''room, angiography'' (EL011) with equipment item ''room, radiographic-fluoroscopic'' (EL014) for the same number of minutes. We are requesting public comment regarding the typical room type used to furnish the services described by these CPT codes, as well as the more general question of the typical room type used for GU and GI procedures. In the past, the RUC has developed broad recommendations regarding the typical uses of rooms for particular procedures, including the radiographic-fluoroscopy room. We believe that such a recommendation from the RUC concerning all of these codes could be useful in ensuring relativity across the PFS.

(9) Penile Trauma Repair (CPT Codes 5443A and 5443B)

CPT created these two new codes because there are no existing codes to capture penile traumatic injury that includes penile fracture, also known as traumatic corporal tear, and complete penile amputation. CPT code 5443A will describe a repair of traumatic corporeal tear(s) while CPT code 5443B will describe a replantation, penis, complete amputation. For CPT code 5443B, we disagree with the RUC recommendation of a work RVU of 24.50. We believe that the 25th

percentile work RVU of 22.10 provides a more accurate value based on the work involved in the procedure and within the context of other codes in the same family, since CPT code 5443A was also valued using the 25th percentile. We find further support for this valuation through a crosswalk to CPT code 43334 (Repair, paraesophageal hiatal hernia via thoracotomy, except neonatal) which has an identical intraservice time and a work RVU of 22.12. Therefore we are proposing a work RVU of 22.10 for CPT code 5443B.

Because CPT codes 5443A and 5443B are typically performed on an emergency basis, we question the appropriateness of the standard 60 minutes of preservice clinical labor in the facility setting, as the typical procedure would not make use of office-based clinical labor. For example, we do not believe that the typical case would require 8 minutes to schedule space in the facility for an emergency procedure, or 20 minutes to obtain consent. We are seeking further public comment on this issue from the RUC and other stakeholders.

(10) Intrastromal Corneal Ring Implantation (CPT Code 657XG)

CPT code 657XG is a new code describing insertion of prosthetic ring segments into the corneal stroma for treatment of keratoconus in patients whose disease has progressed to a degree that they no longer tolerate contact lens wear for visual rehabilitation.

We disagree with the RUC recommendation of a work RVU of 5.93 for CPT code 657XG. Although we appreciated the extensive list of other codes the RUC provided as references, we are concerned that the recommended value for CPT code 657XG overestimates the work involved in furnishing this service relative to other PFS services. We did not find a single code with comparable intraservice and total time that had a higher work RVU. The recommended crosswalk, CPT code 67917 (Repair of ectropion; extensive), appears to have the highest work RVU of any 90-day global surgery service in this range of work time values. It also has longer intraservice time and total time than the code in question, making a direct crosswalk inappropriate.

As a result, we are proposing a new value for CPT code 657XG based on the intraservice time ratio in relation to the recommended crosswalk. We compared the 33 minutes of intraservice time in CPT code 67917 to the 30 minutes of intraservice time in CPT code 657XG. The intraservice time ratio between these two codes is 0.91, and when multiplied by the work RVU of CPT code 67917 (5.93) resulted in a potential work RVU of 5.39. We also considered CPT code 58605 (Ligation or transection of fallopian tube(s)), which has the same intraservice time, seven additional minutes of total time, and a work RVU of 5.28. We believe that CPT 58605 is a closer fit for a direct crosswalk because it shares the same intraservice time of 30 minutes with CPT code 657XG. Accordingly, we are proposing a work RVU of 5.39 for CPT code 657XG.

The RUC recommendation for CPT code 657XG includes a series of invoices for several new supplies and equipment items. One of these was the 10–0 nylon suture with two submitted invoice prices of $245.62 per box of 12, or $20.47 per suture, and another was priced at $350.62 per box of 12, or $29.22 per suture. Given the range of prices between these two invoices, we sought publicly available information and identified numerous sutures that appear to be consistent with those recommended by the specialty society, at lower prices, which we believe are more likely to be typical since we assume that the typical practitioner would seek the best price. One example is ''Surgical Suture, Black Monofilament, Nylon, Size: 10–0, 12''/30cm, Needle: DSL6, 12/bx'' for $146. Therefore, we are proposing to establish a new supply code for ''suture, nylon 10–0'' and price that item at $12.17 each. We welcome comments from stakeholders regarding this supply item.

(11) Dilation and Probing of Lacrimal and Nasolacrimal Duct (CPT Codes 66801, 68810, 68811, 68815 and 68816)

The RUC's review of 10-day global services identified 18 services with greater than 1.5 office visits and 2012 Medicare utilization data over 1,000, including CPT codes 66801, 68810, 68811, 68815, and 68816. As a result, the RUC requested these services be surveyed reviewed for CY 2016.

The RUC recommended a work RVU of 1.00 for CPT code 68801 and a work RVU of 1.54 for CPT code 68810. While we are proposing to use the RUC-recommended work RVU for CPT code 68810, we do not believe the recommendation for CPT code 68801 best reflects the work involved in the procedure because of a discrepancy between the post-operative work time and work RVU. Specifically, the RUC recommendation for the procedure included the removal of a 99211 visit, but the RUC-recommended work RVU did not reflect any corresponding adjustment. As a result, we are proposing to accept the RUC's recommendation to remove the 99211 visit from the service but are proposing to further reduce the work RVU for CPT code 68801 by removing the RVUs associated with CPT code 99211. Therefore, for CY 2016, we are proposing a work RVUs of 0.82 to CPT code 68801 and 1.54 to CPT code 68810.

The RUC recommended a work RVU of 2.03, 3.00, and 2.35 for CPT codes 68811, 68815 and 68816, respectively. We do not believe the RUC recommendations for these services best reflect the work involved in performing these procedures. To value these services, we calculated a total time ratio by dividing the code's current total time by the RUC-recommended total time, and then applying that ratio to the current work RVU. This produces our CY 2016 proposed work RVUs of 1.74, 2.70, and 2.10 for CPT codes 68811, 68815, and 68816, respectively.

(12) Spinal Instability (CPT Code 7208A, 7208B, 7208C, and 7208D)

For CY 2015, the CPT Editorial Panel deleted codes 72010 (radiologic examination, spine, entire, survey study, anteroposterior and lateral), 72069 (radiologic examination, spine, thorocolumbar, standing (scoliosis)), and 72090 (radiological examination, spine; scoliosis study, including supine and erect studies), revised one code, 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views) and created four new codes which cover radiologic examination of the entire thoracic and lumbar spine, including the skull, cervical and sacral spine if performed. The new codes were organized by number of views, ranging from one view in 7208A, two to three views in 7208B, four to five views in 7208C, and minimum of 6 views in 7208D.

We disagree with the RUC's work RVU recommendations for these four codes. For 7208A, we noted that the one minute increase in time resulted in a larger work RVU than would be expected when taking the ratio between time and RVU in the source code and comparing that to the time and work RVU ratio in the new code. Using the relationship between time and RVU from deleted code 72069, we are proposing a work RVU of 0.26 for 7208A, which differs from the RUC-recommended value of 0.30. Using an incremental methodology based on the relationship between work and time in the first code we are proposing to adjust the RUC-recommended work RVUs for CPT codes 7208B, 7208C and 7208D to, respectively, 0.31, 0.35, and 0.41.

(13) Echo Guidance for Ova Aspiration (CPT Code 76948)

In the CY 2014 PFS final rule with comment period, we requested additional information to assist us in the valuation of ultrasound guidance codes. We nominated these codes as potentially misvalued based on the extent to which standalone ultrasound guidance codes were billed separately from services where ultrasound guidance was an integral part of the procedure. CPT code 76948 was among the codes considered potentially misvalued. CPT code 76948 was surveyed by the specialty societies and the RUC issued a recommendation for CY 2016. We have concerns about valuation this code, considering that it is a guidance code used only for a single procedure: 58970 (aspiration of ova), and we believe that these two codes are almost always billed concurrently. We believe codes 76948 and 58970 should be bundled to accurately reflect how the service is furnished.

We are proposing to use work times based on refinements of the RUC-recommended values by removing the 3 minutes of pre and post service time since these times are reflected in the 58970 procedure code. We are proposing work and time values for 76948 based on a crosswalk from 76945 (Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation) which has a physician work time of 30 minutes and an RVU of 0.56. Therefore we are proposing to maintain 25 minutes of intraservice time for 76948 and proposing a work RVU of 0.56.

(14) Immunohistochemistry (CPT Codes 88341, 88342, and 88344)

In establishing interim final direct PE inputs for CY 2015 for CPT codes 88341, 88342, and 88344, we replaced the RUC-recommended supply item ''UltraView Universal DAB Detection Kit'' (SL488) with ''Universal Detection Kit'' (SA117), since the RUC did not provide an explanation for the required use of a more expensive kit. We also adjusted the equipment time for equipment item ''microscope, compound'' (EP024). We re-examined these codes when valuing the immunofluorescence family of codes for CY 2016, and reviewed information received by commenters that explained the need for these supply items. Specifically, commenters explained that the universal detection kit that CMS included in place of the RUC-recommended kit was not typically used in these services as it was not clinically appropriate. We are proposing to include the RUC-recommended supply item, SL488, for CPT codes 88341, 88342, and 88344, as well as the RUC-recommended equipment time for ''microscope, compound'' for CY 2016.

(15) Immunofluorescent Studies (CPT Codes 88346 and 8835X)

For CY 2016, the CPT Editorial Panel deleted one code, CPT 88347 (Antibody evaluation), created a new add-on service, CPT 8835X, and revised CPT code 88346 to describe immunofluorescent studies. The RUC recommended a work RVU of 0.74 for CPT code 88346 and 0.70 for CPT code 8835X. While we are accepting the RUC recommendation for CPT code 88346, we do not believe the recommendation for CPT code 8835X best reflects the work involved in the procedure due to our concerns with the relationship between the RUC-recommended intraservice times for the base code and the newly created add-on code. We examined intraservice time relationships between other base codes and add-on codes and found that two codes in the Intravascular ultrasound family, CPT 37250 (Ultrasound evaluation of blood vessel during diagnosis or treatment) and 37251(Ultrasound evaluation of blood vessel during diagnosis or treatment), share a similar base code/add-on code intraservice time relationship, and are also diagnostic in nature, as are CPT codes 88346 and 8835X. Due to these similarities, we believe it is appropriate to apply the relationship, which is a 24 percent difference, between CPT codes 37250 and 37251 in calculating work RVUs for CPT codes 88346 and 8835X. Multiplying the RVU of CPT code 88346, 0.74, by 24 percent, and then subtracted the product from 0.74 results in a work RVU of 0.56 for CPT code 8835X. Therefore, for CY 2016, we are proposing a work RVU of 0.74 for CPT code 88346 and 0.56 for CPT code 8835X.

(16) Morphometric Analysis (CPT Codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369)

CPT codes 88367 and 88368 were reviewed and valued in the CY 2015 PFS final rule with comment period (79 FR 67668 through 67669). Since then, the RUC has re-reviewed these services for CY 2016 due to the specialty society's initially low survey response rate. In our review of these codes, we noticed that the latest RUC recommendation is identical to the RUC recommendation provided for CY 2015 rulemaking. As a result, we do not believe there is any reason to modify our CY 2015 work RVUs or work time for these procedures. Therefore, we are proposing to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016.

In establishing interim final direct PE inputs for CY 2015 for CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369, we refined the RUC-recommended direct PE inputs as follows. We refined the units of several supply items, including ''ethanol, 100%'' (SL189), ''ethanol, 70%'' (SL190), ''ethanol, 85%'' (SL191), ''ethanol, 95%'' (SL248), ''kit, FISH paraffin pretreatment'' (SL195), ''kit, HER–2/neu DNA Probe'' (SL196), positive and negative control slides (SL112, SL118, SL119, SL184, SL185, SL508, SL509, SL510, SL511), ''(EBER) DNA Probe Cocktail'' (SL497),''Kappa probe cocktails'' (SL498) and ''Lambda probe cocktails'' (SL499), to maintain consistency within the codes in the family, and adjusted the quantities included in these codes to align with the code descriptors and better reflect the typical resources used in furnishing these services. We also adjusted the equipment time for equipment items ''water bath, FISH procedures (lab)'' (EP054), ''chamber, Hybridization'' (EP045), ''microscope, compound'' (EP024), ''instrument, microdissection (Veritas)'' (EP087), and ''ThermoBrite'' (EP088), to reflect the typical time the equipment is used, among other common refinements.

We re-examined these codes when valuing the immunofluorescence family of codes for CY 2016, and reviewed information received from commenters that described the typical batch size for each of these services, thereby explaining the apparent inconsistencies and discrepancies in the quantity of units among the codes in the family. We are proposing to include the RUC-recommended quantities for each of these supply items for the CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369 for CY 2016. With regard to the equipment items, we received information explaining that the recommended equipment times already accounted for the typical batch size, and thus, the recommended times were already reflective of the typical case. Therefore, we are proposing to adjust the equipment time for equipment items EP054, EP045, and EP087 to align with the RUC-recommended times. We also received comments explaining the need for equipment item EP088. Based on that information, we are proposing to include this equipment item consistent with the RUC recommendations for CPT code 88366.

We note that the information we received regarding the typical batch size

was critical in determining the appropriate direct PE inputs for these pathology services. We also note that we usually do not have information regarding the typical batch size or block size when we are reviewing the direct PE inputs for pathology services. The supply quantity and equipment minutes are often a direct function of the number of tests processed at once. Given the importance of the typical number of tests being processed by a laboratory in determining the direct PE inputs, which often include expensive supplies, we are very concerned that the direct PE inputs included in many pathology services may not reflect the typical resource costs involved in furnishing the typical service.

In particular, we note that since laboratories of various sizes furnish pathology tests and that, depending on the test, a large laboratory may be at least as likely to have furnished a test to a Medicare beneficiary compared to a small laboratory, we believe that an equipment item included in a recommendation that is commercially available to a small laboratory may not be the same equipment item that is used in the typical case. If the majority of services billed under the PFS for a particular CPT code are furnished by laboratories that run many of these tests each day, then assumptions informed by commercially available products may significantly underestimate the typical number of tests processed together, and thus the assumptions underlying current valuations for per-test cost of supplies and equipment may be much higher than the typical resources used in furnishing the service. We invite stakeholders to provide us with information about the equipment and supply inputs used in the typical case for particular pathology services.

(17) Vestibular Caloric Irrigation (CPT Codes 9254A and 9254B)

For CY 2016, the CPT Editorial Panel deleted CPT code 92543 (Assessment and recording of balance system during irrigation of both ears) and created two new CPT codes, 9254A and 9254B, to report caloric vestibular testing for bithermal and monothermal testing procedures, respectively. The RUC recommended a work RVU of 0.80 for CPT code 9254A and a work RVU of 0.55 for CPT code 9254B. We believe the recommendations for these services overstate the work involved in performing these procedures. Due to similarity in service and time, we believe a direct crosswalk of CPT code 97606 (Negative pressure wound therapy, surface area greater than 50 square centimeters, per session) to CPT code 9254A is appropriate. To value CPT code 9254B, we divided the proposed work RVU for 9254A in half since the code descriptor for this procedure describes the service as having two irrigations as opposed to the four involved in 9254A. Therefore, for CY 2016, we are proposing a work RVUs of 0.60 to 9254A and 0.30 to 9254B.

(18) Instrument-Based Ocular Screening (CPT Codes 99174 and 9917X)

For CY 2015, the CPT Editorial Panel created a new code, CPT code 9917X, to describe instrument-based ocular screening with on-site analysis and also revised existing CPT code 99174, which describes instrument-based ocular screening with remote analysis and report. Currently, CPT code 99174 is assigned a status indicator of N (non-covered service) which we believe should be maintained due to its nature as a screening service. After review of CPT code 9917X, we believe this service is also a screening service and should be assigned a status indicator of N (non-covered service). Therefore, for CY 2016, we are proposing to assign a PFS status indicator of N (non-covered service) for CPT codes 99174 and 9917X.

(19) Low-Dose Computer Tomography, Lung, Screening (GXXX1) and Lung Cancer Screening Counseling and Shared Decision Making Visit (GXXX2)

We have issued national coverage determination (NCD) for the coverage of a lung cancer screening counseling and shared decision making visit and, for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The American College of Radiology (ACR) submitted recommendations for work and direct PE inputs. The ACR recommended that we crosswalk GXXX1 to 71250 (computed tomography, thorax; without contrast material) with additional physician work added to account for the added intensity of the service. After reviewing this recommendation, we believe that the physician work (time and intensity) is identical in both GXXX1 and 71250, and therefore, we are proposing a work RVU of 1.02 for GXXX1.

We are proposing to value the lung cancer screening counseling and shared decision making visit (GXXX2) using a crosswalk from the work value for G0443 (Brief face-to-face counseling for alcohol misuse, 15 minutes) which has a work RVU of 0.45. We added 2 minutes of pre-service time, and 1 minute post-service time which we valued at 0.0224 RVU per minute yielding a total of 0.062 additional RVUs which we then added to 0.45, bringing the total proposed work RVUs for GXXX2 to 0.52. The direct PE input recommendations from the ACR were refined according to CMS standard refinements and appear in the CY 2016 proposed direct PE input database.

7. Direct PE Input-Only Recommendations

In CY 2014, we proposed to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. In developing the proposal, we sought a reliable means for Medicare to set upper payment limits for office-based procedures given our several longstanding concerns regarding the accuracy of certain aspects of the direct PE inputs, including both items and procedure time assumptions, and prices of individual supplies and equipment (78 FR 74248 through 74250). After considering the many comments we received regarding our proposal, the majority of which urged us to withdraw the proposal for a variety of reasons, we decided not to finalize the policy. However, we continue to believe that using practice expense data that are auditable, comprehensive, and regularly updated would contribute to the accuracy of practice expense calculations.

Subsequent to our decision not to finalize the proposal, the RUC forwarded direct PE input recommendations for a subset of codes with nonfacility PE RVUs that would have been limited by the policy. Some of these codes also include work values, but the RUC recommendations did not address the accuracy of those values.

We generally believe that combined reviews of work and PE for each code under the potentially misvalued codes initiative leads to more accurate and appropriate assignment of RVUs. We also believe, and have previously stated, that our standard process for evaluating potentially misvalued codes is unlikely to be the most effective means of addressing our concerns regarding the accuracy of some aspects of the direct PE inputs (79 FR 74248).

However, we also believe it is important to use the most accurate and up-to-date information available to us when developing PFS RVUs for individual services. Therefore, we have reviewed the RUC-recommended direct PE inputs for these services and are proposing to use them, with the refinements addressed in this section. However, we are also identifying these

codes as potentially misvalued because their direct PE inputs were not reviewed alongside review of their work RVUs and time. We considered not addressing these recommendations until such time as comprehensive reviews could occur, but we recognized the public interest in using the updated recommendations regarding the PE inputs until such time as the work RVUs and time can be addressed. Therefore, we note that while we are proposing adjusted PE inputs for these services based on these recommendations, we would anticipate addressing any corresponding change to direct PE inputs once the work RVUs and time are addressed.

a. Repair of Nail Bed (CPT Code 11760)

This recommendation includes 22 minutes of clinical labor time assigned for ''Assist physician in performing procedure.'' Because CPT code 11760 has 33 minutes of work intraservice time, we believe that this clinical labor input was intended to be calculated at 67 percent of work time. However, the equipment times are also calculated based on the 22 minutes of intraservice time. We are seeking comment on whether or not it would be appropriate to include the full 33 minutes of work intraservice time for the equipment.

b. Submucosal Ablation of the Tongue Base (CPT Code 41530)

We did not review CPT code 41530 for direct PE inputs, because we noted that the RUC anticipates making recommendations regarding the work RVU and direct PE inputs for this service in the near future.

c. Cytopathology Fluids, Washings or Brushings (CPT Codes 88104, 88106, 88108)

We are proposing to update the Millipore filter supply (SL502) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we are proposing to crosswalk the price of the Millipore filter to the cytology specimen filter (Transcyst) supply (SL041) and assign a value of $4.15. This change is reflected in the proposed direct PE input database.

d. Cytopathology Smears, Screening and Interpretation (CPT Codes 88160, 88161, 88162)

We are concerned that there is a lack of clarity and the possibility for confusion contained in the CPT descriptors of CPT codes 88160 and 88161. The CPT descriptor for the first code refers to the ''screening and interpretation'' of Cytopathology smears, while the descriptor for the second code refers to the ''preparation, screening and interpretation'' of Cytopathology smears. We believe that there is currently the potential for duplicative counting of direct PE inputs due to the overlapping nature of these two codes. We are concerned that the same procedure may be billed multiple times under both CPT code 88160 and 88161. We believe that these codes are potentially misvalued, and we are seeking a full review of this family of codes for both work and PE, given the potential for overlap. We recognize that the ideal solution may involve revisions by the CPT Editorial Panel.

With regard to the current direct PE input recommendations, we are proposing to remove the clinical labor minutes recommended for ''Stain air dried slides with modified Wright stain'' for CPT code 88160 since staining slides would not be a typical clinical labor task if there is no slide preparation taking place, as the descriptor for this code suggests.

We are proposing to update the protease solution supply (SL506) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we are proposing to change the name of the supply to ''Protease'', alter the unit of measurement from milliliters to milligrams, change the quantity assigned to CPT code 88182 from 1 to 1.12, and update the price from $0.47 to $0.4267. These changes are reflected in the proposed direct PE input database.

We are requesting additional information regarding the use of the desktop computer with monitor (ED021) for CPT code 88182. We have made no change to the current equipment time value pending the submission of additional information.

e. Flow Cytometry, Cytoplasmic Cell Surface (CPT Code 88184, 88185)

We are requesting additional information regarding the specific use of the desktop computer with monitor (ED021) for CPT codes 88184 and 88185 since the recommendation does not specify how it is used.

f. Consultation on Referred Slides and Materials (CPT Codes 88321, 88323, 88325)

We are proposing to remove the clinical labor time for ''Accession specimen/prepare for examination'' for CPT codes 88321 and 88325. These codes do not involve the preparation of slides, so this clinical labor task is duplicative with the labor carried out under ''Open shipping package, remove and sort slides based on outside number.'' We are proposing to maintain the recommended 4 minutes for this clinical labor task for CPT code 88323, since it does require slide preparation.

We are proposing to refine the clinical labor time for ''Register the patient in the information system, including all demographic and billing information'' from 13 minutes to 5 minutes for all three codes. As indicated in Table 6, our proposed standard clinical labor time for entering patient data is 4 minutes for pathology codes, and we believe that the extra tasks involving label preparation described in this clinical labor task would typically require an additional 1 minute to complete. We also believe that the additional recommended time likely reflects administrative tasks that are appropriately accounted for in the indirect PE methodology.

We are proposing to refine the clinical labor time from 7 minutes to 5 minutes for the new task ''Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit, including muscle biopsy clamp as needed. Review with sender instructions for preservation of specimen integrity and return arrangements. Contact courier and arrange delivery to referring laboratory/facility.'' Based on the description of this task, we believe that this task would typically take 5 minutes to be performed by the Lab Technician.

We are proposing to remove the eosin solution supply (SL063) from CPT code 88323. We do not agree that this supply would be typically used in this procedure, and the eosin solution is redundant when used together with the hematoxylin stain supply (SL135). We are also refining the quantity of the hematoxylin stain from 32 to 8 for CPT code 88323, to be consistent with its use in other related Pathology codes.

We are proposing to remove many of the inputs for clinical labor, supplies, and equipment for CPT code 88325. The descriptor for this code indicates that it does not involve slide preparation, and therefore we are proposing labor, supplies, and equipment inputs to match the inputs recommended for CPT code 88321, which also does not include the preparation of slides.

g. Morphometric Analysis, Tumor Immunohistochemistry (CPT Codes 88360, 88361)

We are proposing to update the pricing for the Benchmark ULTRA automated slide preparation system (EP112) and the E-Bar II Barcode Slide Label System (EP113). Based on stakeholder submission of information subsequent to the original RUC recommendation, we are reclassifying

these two pieces of equipment as a single item with a price of $150,000. CPT codes 88360 and 88361 have been valued using this new price. The equipment time values remain unchanged.

The RUC recommendation for CPT codes 88360 and 88361 included an invoice for the Antibody Estrogen Receptor monoclonal supply (SL493). The submitted invoice has a price of $694.70 per box of 50, or $13.89 per test. We sought publically available information regarding this supply and identified numerous monoclonal antibody estrogen receptors that appear to be consistent with those recommended by the specialty society, at publicly available lower prices, which we believe are more likely to be typical since we assume that the typical practitioner would seek the best price available to the public. One example is Estrogen Receptor Antibody (h-151) [DyLight 405], priced at 100 tests per box for $319. Therefore, we are proposing to establish a new supply code for ''Antibody Estrogen Receptor monoclonal'' and price that item at $3.19 each. We welcome comments from stakeholders regarding this supply item.

h. Nerve Teasing Preparations (CPT Code 88362)

We are proposing to refine the recommended clinical labor time for ''Assist pathologist with gross specimen examination including the following; Selection of fresh unfixed tissue sample; selection of tissue for formulant fixation for paraffin blocking and epon blocking. Reserve some specimen for additional analysis'' from 10 minutes to 5 minutes. We note that the 5 minutes includes 3 minutes for assisting the pathologist with the gross specimen examination (as listed in Table 6) and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen.

i. Nasopharyngoscopy With Endoscope (CPT Code 92511)

We are proposing to remove the endosheath (SD070) from this procedure, because we do not believe it would be typically used and it was not included in the recommendations for any of the other related codes in the same tab. If the endosheath were included as a supply with the presentation of additional clinical information, then we believe it would be appropriate to remove all of the clinical labor and equipment time currently assigned to cleaning the scope.

j. Needle Electromyography (CPT Codes 95863, 95864, 95869, 95870)

We are proposing to reduce the quantity of the iontophoresis electrode kit (SA014) supply from 4 to 3. According to the description of this code, the procedure typically uses 2–4 electrodes, and therefore we believe that a supply quantity of 3 would better reflect the typical case. We are requesting further information regarding the typical number of electrodes used in this procedure; if the maximum of 4 electrodes is in fact typical for the procedure, then we recommend that the code descriptor be referred to CPT for further clarification.

J. 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 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 that are not integrated into an electronic health record system 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 an 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 Medicare Administrative Contractors 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 fee under the PFS a facility fee 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 areas (MSAs).

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 Rural Health Policy (ORHP) 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 *www.cms.gov/teleheath/*.

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. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in furnishing the candidate telehealth service produces 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 covered telehealth services, see the CMS Web site at *www.cms.gov/teleheath/*. 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 2015 will be considered for the CY 2017 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, requestors 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 *www.cms.gov/telehealth/*.

3. Submitted Requests to the List of Telehealth Services for CY 2016

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 with respect to 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, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

a. Submitted Requests

We received several requests in CY 2014 to add various services as Medicare telehealth services effective for CY 2016. The following presents a discussion of these requests, and our proposals for additions to the CY 2016 telehealth list. Of the requests received, we find that the following services are sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category one basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2016:

• CPT code 99356 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service); and 99357 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service).

The prolonged service codes can only be billed in conjunction with hospital inpatient and skilled nursing facility evaluation & management (E/M) codes, and of these, only subsequent hospital and subsequent nursing facility visit codes are on list of Medicare telehealth services. Therefore, CPT codes 99356 and 99357 would only be reportable with codes for which limits of one subsequent hospital visit every three days via telehealth, and one subsequent nursing facility visit every thirty days, would continue to apply.

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

Although these services are for home-based dialysis, and a patient's home is not an authorized originating site for telehealth, we recognize that many components of these services would be furnished from an authorized originating site and, therefore, can be furnished via telehealth.

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, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA). An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment (MCP) code and the 4 or more visit MCP code. See the final rule for CY 2005 (69 FR 66276) for further information on furnishing ESRD services via telehealth.

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:

• All evaluation and management services, telerehabilitation services, and palliative care, pain management and patient navigation services for cancer patients.

None of these requests identified the specific codes that were being requested for addition as telehealth services, and two of the requests did not include evidence of any clinical benefit when the services are furnished via telehealth. Since we did not have information on the specific codes requested for addition or evidence of clinical benefit for these requests, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list.

• 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 consider critical care services 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 would consider 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. 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 request, which 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 produces a clinical benefit for the patient. However, in reviewing the information provided by the ATA and a study entitled, ''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 TM significantly reduced mortality rates or hospital length of stay, we do not believe that the evidence demonstrates a clinical benefit to patients. Therefore, we are not proposing to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016.

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

As we indicated in the CY 2015 PFS final rule with comment period (79 FR 67600), these services are not separately payable by Medicare. It would be inappropriate to include a service as a telehealth service when Medicare does not otherwise make a separate payment for it. Therefore, we are not proposing to add these non-payable services to the list of Medicare telehealth services for CY 2016.

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

As we indicated in the CY 2014 PFS final rule with comment period (78 FR 74403), we assigned a status indicator of ''N'' (Noncovered service) to this service because: (1) this service is non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT code 99444 is currently noncovered, there would be no Medicare payment if this service was furnished without the use of a telecommunications system. Since this service is noncovered under Medicare, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

• CPT code 99490 (chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored).

This service is one that can be furnished without the beneficiary's face-to-face presence, and using any number of non-face-to-face means of communication. Therefore, the service is not appropriate for consideration as a Medicare telehealth service. It is unnecessary to add this service to the list of Medicare telehealth services. Therefore, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

• CPT codes 99605 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient); 99606 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient); and 99607 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes (list separately in addition to code for primary service).

These codes are noncovered services for which no payment may be made under the PFS. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2016.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2016 on a category 1 basis: Prolonged service inpatient CPT codes 99356 and 99357 and ESRD-related services 90933 through 90936. As indicated above, the prolonged service codes can only be billed in conjunction with subsequent hospital and subsequent nursing facility codes. Limits of one subsequent hospital visit every three days, and one subsequent nursing facility visit every thirty days, would continue to apply when the services are furnished as telehealth services. For the ESRD related services, 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, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA).

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 2017, these requests must be submitted and received by December 31, 2015. 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 *www.cms.gov/telehealth/.*

4. Proposal To Amend § 410.78 To Include Certified Registered Nurse Anesthetists as Practitioners for Telehealth Services

Under section 1834(m)(1) of the Act, Medicare makes payment for telehealth services furnished by physicians and practitioners. Section 1834(m)(4)(E) of the Act specifies that, for purposes of furnishing Medicare telehealth services, the term ''practitioner'' has the meaning given that term in section 1842(b)(18)(C), which includes a certified registered nurse anesthetist (CRNA) as defined in section 1861 (bb)(2).

We initially omitted CRNAs from the list of distant site practitioners for telehealth services in the regulation because we did not believe these practitioners would furnish any of the service on the list of Medicare telehealth services. However, CRNAs in some states are licensed to furnish certain services on the telehealth list, including E/M services. Therefore, we propose to revise the regulation at § 410.78(b)(2) to include a CRNA, as described under § 410.69, to the list of distant site practitioners who can furnish Medicare telehealth services.

K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

1. Background

Section 1861(s)(2)(A) of the Act establishes the benefit category for services and supplies furnished as ''incident to'' the professional services of a physician. The statute specifies that services and supplies furnished as an incident to a physician's professional service (hereinafter ''incident to services'') are ''of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills.'' In addition to the requirements of the statute, § 410.26 sets forth specific requirements that must be met for physicians and other practitioners to bill Medicare for incident to services. Section 410.26(a)(7) limits incident to services to those included under section 1861(s)(2)(A) of the Act and that are not covered under another benefit category. Section 410.26(b) specifies (in part) that in order for services and supplies to be paid as incident to services under Medicare Part B, the services or supplies must be:

• Furnished in a noninstitutional setting to noninstitutional patients.

• An integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

• Furnished under direct supervision (as specified under § 410.26(a)(2)) of a physician or other practitioner eligible to bill and directly receive Medicare payment.

• Furnished by a physician, a practitioner with an incident to benefit, or auxiliary personnel.

In addition to § 410.26, there are regulations specific to each type of practitioner who is allowed to bill for incident to services as specified in § 410.71(a)(2) (clinical psychologist services), § 410.74(b) (physician assistants' services), § 410.75(d) (nurse practitioners' services), § 410.76(d) (clinical nurse specialists' services), and § 410.77(c) (certified nurse-midwives' services). When referring to practitioners who can bill for services furnished incident to their professional services, we are referring to physicians and these practitioners.

Incident to services are treated as if they were furnished by the billing physician or other practitioner for purposes of Medicare billing and payment. Consistent with this terminology, in this discussion when referring to the physician or other practitioner furnishing the service, we are referring to the physician or other practitioner who is billing for the incident to service. When we refer to the ''auxiliary personnel'' or the person who provides the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the physician or other practitioner who bills for the incident to service.

Since we treat incident to services as services furnished by the billing physician or other practitioner for

purposes of Medicare billing and payment, payment is made to the billing physician or other practitioner under the PFS, and all relevant Medicare rules apply including, but not limited to, requirements regarding medical necessity, documentation, and billing. Those practitioners who can bill Medicare for incident to services are paid at their applicable Medicare payment rate as if they personally furnished the service. For example, when incident to services are billed by a physician, they are paid at 100 percent of the fee schedule amount, and when the services are billed by a nurse practitioner or clinical nurse specialist, they are paid at 85 percent of the fee schedule amount. Payments are subject to the usual deductible and coinsurance amounts.

In the CY 2014 PFS final rule with comment period, we amended § 410.26 by adding a paragraph (b)(7) to require that, as a condition for Medicare Part B payment, all incident to services must be furnished in accordance with applicable state law. Additionally, we amended the definition of auxiliary personnel at § 410.26(a)(1) to require that the individual who provides the incident to services must meet any applicable requirements to provide such services (including licensure) imposed by the state in which the services are furnished. These requirements for compliance with applicable state laws apply to any individual providing incident to services as a means to protect the health and safety of Medicare beneficiaries in the delivery of health care services, and to provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services that are not furnished in compliance with state law (78 FR 74410). Revisions to § 410.26(a)(1) and (b)(7) were intended to clarify the longstanding payment policy of paying only for services that are furnished in compliance with any applicable state or federal requirements. The amended regulations also provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services that are not furnished in compliance with applicable requirements.

2. Billing Physician as the Supervising Physician

In addition to the CY 2014 revisions to the regulations for incident to services, we believe that additional requirements for incident to services should be explicitly and unambiguously stated in the regulations. As described in this proposed rule, incident to a physician's or other practitioner's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's or other practitioner's personal professional services in the course of diagnosis or treatment of an injury or illness (§ 410.26(b)(2)). Incident to services require direct supervision of the auxiliary personnel providing the service by the physician or other practitioner (§ 410.26(b)(5)).

We are proposing to revise the regulations specifying the requirements for which physicians or other practitioners can bill for incident to services. In the CY 2002 PFS final rule, in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, at 66 FR 55267, we stated that when a claim is submitted to Medicare under the billing number of a physician or other practitioner for an 'incident to' service, the physician or other practitioner is stating that he or she performed the service or directly supervised the auxiliary personnel performing the service. Accordingly, the Medicare billing number of the ordering physician or other practitioner should not be used if that person did not directly supervise the auxiliary personnel.

Section 410.26(b)(5) currently states 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. To be certain that the incident to services furnished to a beneficiary are in fact an integral, although incidental, part of the physician's or other practitioner's personal professional service that is billed to Medicare, we believe that the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service. It has been our position that billing practitioners should have a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment as an incident to their own professional services. This is consistent with the requirements that all physicians and billing practitioners attest on each Medicare claim that he or she ''personally furnished'' the services for which he or she is billing. Without this requirement, there could be an insufficient nexus with the physician's or other practitioner's services being billed on a claim to Medicare as incident to services and the actual services being furnished to the Medicare beneficiary by the auxiliary personnel. Therefore, we are proposing to amend § 410.26(b)(5) to state that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services. Also, to further clarify the meaning of the proposed amendment to this regulation, we are proposing to remove the last sentence from § 410.26(b)(5) specifying 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.

3. Auxiliary Personnel Who Have Been Excluded or Revoked From Medicare

As a condition of Medicare payment, auxiliary personnel who, under the direct supervision of a physician or other practitioner, provide incident to services to Medicare beneficiaries must comply with all applicable Federal and State laws. This includes not having been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General. We are proposing to amend the regulation to explicitly prohibit auxiliary personnel from providing incident to services who have either been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or who have had their enrollment revoked for any reason. These excluded or revoked individuals are already prohibited from providing services to Medicare beneficiaries, so this proposed revision is an additional safeguard to ensure that these excluded or revoked individuals are not providing incident to services and supplies under the direct supervision of a physician or other authorized supervising practitioner. These proposed revisions to the incident to regulations will provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services and supplies that are not furnished in compliance with our program requirements.

4. Compliance and Oversight

We recognize that there are many ways in which compliance with these requirements could be consistently and fairly assured across the Medicare program. In considering implementation of these proposals, we wish to be mindful of the need to minimize or eliminate any practitioner administrative burden while at the same time ensuring that practitioners are not subjected to unnecessary audits or

placed at risk of inadvertent non-compliance. Therefore, while we believe that the initial responsibility of compliance rests with the practitioner, we invite comments through this proposed rule about possible approaches we could take to improve our ability ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations. We invite commenters to consider the options we will consider, such as creating new categories of enrollment, implementing a mechanism for registration short of full enrollment, requiring the use of claim elements such as modifiers to identify the types of individuals providing services, or relying on post-payment audits, investigations and recoupments by CMS contractors such as Recovery Auditors or Program Integrity Contractors. We will consider these comments in the course of implementing the proposals we finalize in rulemaking for CY 2016, and further, if we decide in the future that additional regulations or guidance will be necessary to monitor compliance with these or other requirements surrounding incident to services.

L. Portable X-ray: Billing of the Transportation Fee

Portable X-ray suppliers receive a transportation fee for transporting portable X-ray equipment to the location where portable X-rays are taken. If more than one patient at the same location is X-rayed, the portable X-ray transportation fee is allocated among the patients. We have received feedback that some portable x-ray suppliers have been operating under the assumption that the prorated transportation payment when more than one patient is receiving portable X-ray services at the same location refers to only a subset of patients. The Medicare Claims Processing Manual (Pub. 100–4, Chapter 13, Section 90.3) currently states:

> Carriers shall allow only a single transportation payment for each trip the portable X-ray supplier makes to a particular location. When more than one Medicare patient is X-rayed at the same location, e.g., a nursing home, prorate the single fee schedule transportation payment among all patients receiving the services. For example, if two patients at the same location receive X-rays, make one-half of the transportation payment for each.

In some jurisdictions, Medicare contractors have been allowing the portable X-ray transportation fee to be allocated only among Medicare Part B beneficiaries. In other jurisdictions, Medicare contractors have required the transportation fee to be allocated among all Medicare patients (Parts A and B). We believe it would be more appropriate to allocate the transportation fee among all patients who receive portable X-ray services in a single trip. Medicare should not pay for more than its share of the transportation costs for portable X-ray services.

We are proposing to revise the Medicare Claims Processing Manual (Pub. 100–4, Chapter 13, Section 90.3) to remove the word ''Medicare'' before ''patient'' in section 90.3. We are also proposing to clarify that this subregulatory guidance means that, when more than one patient is X-rayed at the same location, the single transportation payment under the PFS is to be prorated among all patients (Medicare Parts A and B, and non-Medicare) receiving portable X-ray services during that trip, regardless of their insurance status.

For example, for portable x-ray services furnished at a SNF, we believe that the transportation fee should be allocated among all patients receiving portable X-ray services at the same location in a single trip irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. If the patient is in a Part A SNF stay, payment for the allocated portion of the transportation fee (and the X-ray) would be the SNF's responsibility. For a privately insured patient, it would be the responsibility of that patient's insurer. For a Medicare Part B patient, payment would be made under Part B for the share of the transportation fee attributable to that patient. We welcome comments on this proposal to determine Medicare Part B's portion of the transportation payment by prorating the single fee among all patients.

M. Technical Correction: Waiver of Deductible for Anesthesia Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test

Section 1833(b)(1) of the Act waives the deductible for colorectal cancer screening tests regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. To implement this statutory provision, we amended our regulation at § 410.160 to add to the list of services to which the deductible does not apply, beginning January 1, 2011, a surgical service furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

In the CY 2015 PFS final rule with comment period, we modified the regulatory definition of colorectal cancer screening test with regard to colonoscopies to include anesthesia services whether billed as part of the colonoscopy service or separately. (See § 410.37(a)(1)(iii) of our regulations). In the preamble to the final rule, we stated that the statutory waiver of deductible would apply to anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during a colonoscopy (79 FR 67731). We also indicated that practitioners should report anesthesia services with the PT modifier in such circumstances. The final policy was implemented for services furnished during CY 2015. While we modified the definition of colorectal cancer screening services in the regulation at § 410.37(a)(1)(iii) to include anesthesia furnished with a screening colonoscopy, we did not make a conforming change to our regulations to expressly reflect the inapplicability of the deductible to those anesthesia services.

To better reflect our policy in the regulations, we propose a technical correction to amend § 410.160(b)(8) to expressly recognize anesthesia services. Specifically, we propose to amend § 410.160(b)(8) to add ''and beginning January 1, 2015, for an anesthesia service,'' following the first use of the phrase ''a surgical service'' and to add ''or anesthesia'' following the word ''surgical'' each time it is used in the second sentence of § 410.160(b)(8). This amendment to our regulation will ensure that both surgical or anesthesia services furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test will be exempt from the deductible requirement when furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

III. Other Provisions of the Proposed Regulations

A. Proposed Provisions associated with the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—
++ Basic Life Support (BLS) (emergency and non-emergency)
++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency)
++ Advanced Life Support, Level 2 (ALS2)
++ Paramedic ALS Intercept (PI)
++ Specialty Care Transport (SCT)
- For Air—
++ Fixed Wing Air Ambulance (FW)
++ Rotary Wing Air Ambulance (RW)

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through December 31, 2017. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2018. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2017. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2018 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS

final rule with comment period (78 FR 74439 through 74440)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2017, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Changes in Geographic Area Delineations for Ambulance Payment

a. Background

In the CY 2015 PFS final rule with comment period (79 FR 67744 through 67750) as amended by the correction issued December 31, 2014 (79 FR 78716 through 78719), we adopted, beginning in CY 2015, the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the Rural-Urban Commuting Area (RUCA) codes for purposes of payment under the ambulance fee schedule. With respect to the updated RUCA codes, we designated any census tracts falling at or above RUCA level 4.0 as rural areas. In addition, we stated that none of the super rural areas would lose their status upon implementation of the revised OMB delineations and updated RUCA codes. After publication of the CY 2015 PFS final rule with comment period and the correction, we received feedback and comments from stakeholders expressing concerns about the implementation of the new geographic area delineations finalized in that rule (as corrected). In response to these concerns, we are clarifying our implementation of the revised OMB delineations and the updated RUCA codes in CY 2015, and reproposing the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent calendar years. We are requesting public comment on our proposals, as further discussed in section III A.3.b. of this proposed rule.

b. Provisions of the Proposed Rule

Under section 1834(l)(2)(C) of the Act, the Secretary is required to consider appropriate regional and operational differences in establishing the ambulance fee schedule. Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to take into account appropriate regional (urban and rural) differences. This use of consistent geographic standards for Medicare payment purposes provides for consistency across the Medicare program.

The geographic areas used under the ambulance fee schedule effective in CY 2007 were based on OMB standards published on December 27, 2000 (65 FR 82228 through 82238), Census 2000 data, and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). For a discussion of OMB's delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the ambulance fee schedule, we refer readers to the preamble of the CY 2007 Ambulance Fee Schedule proposed rule (71 FR 30358 through 30361) and the CY 2007 PFS final rule with comment period (71 FR 69712 through 69716). On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* According to OMB, this bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data. OMB defines an MSA as a CBSA associated with at least one urbanized area that has a population of at least 50,000, and a Micropolitan Statistical Area (referred to in this discussion as a Micropolitan Area) as a CBSA associated with at least one urban cluster that has a population of at least 10,000 but less than 50,000 (75 FR 37252). Counties that do not qualify for inclusion in a CBSA are deemed ''Outside CBSAs.'' We note that, when referencing the new OMB geographic boundaries of statistical areas, we are using the term ''delineations'' consistent with OMB's use of the term (75 FR 37249).

Although the revisions OMB published on February 28, 2013 were not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin did contain a number of significant changes. For example, there are new CBSAs, urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745), we reviewed our findings and impacts relating to the new OMB delineations, and found no compelling reason to further delay implementation. We stated in the CY 2015 final rule with comment period, and we continue to believe, that it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2015 IPPS final rule (79 FR 49952), we adopted OMB's revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. For the reasons discussed in this section above, we believe that it would be appropriate to adopt the same geographic area delineations for use under the ambulance fee schedule as are used under the IPPS and other Medicare payment systems. Thus, we are proposing to continue implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We continue to believe that the updated OMB delineations more realistically reflect rural and urban populations, and that the use of such delineations under the ambulance fee schedule would result in more accurate payment. Under the ambulance fee schedule, consistent with our current definitions of urban and rural areas (§ 414.605), in CY 2016 and subsequent CYs, MSAs would continue to be recognized as urban areas, while Micropolitan and other areas outside MSAs, and rural census tracts within MSAs (as discussed below in this section), would continue to be recognized as rural areas. We invite public comments on this proposal.

In addition to the OMB's statistical area delineations, the current geographic areas used in the ambulance fee schedule also are based on rural census tracts determined under the most recent version of the Goldsmith Modification. These rural census tracts within MSAs are considered rural areas under the ambulance fee schedule (see § 414.605). For certain rural add-on payments, section 1834(l) of the Act requires that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. In the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the

Goldsmith Modification, designated as RUCA codes. RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716) and the CY 2015 PFS final rule with comment period (79 FR 67745 through 67746). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service Web site for a detailed listing of updated RUCA codes found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. The updated RUCA code definitions were introduced in late 2013 and are based on data from the 2010 decennial census and the 2006–2010 American Community Survey. Information regarding the American Community Survey can be found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. We believe that the most recent RUCA codes provide more accurate and up-to-date information regarding the rurality of census tracts throughout the country. Accordingly, we are proposing to continue to use the most recent modifications of the RUCA codes for CY 2016 and subsequent CYs, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. If we continue to use the most recent RUCA codes, many counties that are designated as urban at the county level based on population would continue to have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745), the 2010 Primary RUCA codes are as follows:

(1) Metropolitan area core: primary flow with an urbanized area (UA).

(2) Metropolitan area high commuting: primary flow 30 percent or more to a UA.

(3) Metropolitan area low commuting: primary flow 10 to 30 percent to a UA.

(4) Micropolitan area core: primary flow within an Urban Cluster of 10,000 to 49,999 (large UC).

(5) Micropolitan high commuting: primary flow 30 percent or more to a large UC.

(6) Micropolitan low commuting: primary flow 10 to 30 percent to a large UC.

(7) Small town core: primary flow within an Urban Cluster of 2,500 to 9,999 (small UC).

(8) Small town high commuting: primary flow 30 percent or more to a small UC.

(9) Small town low commuting: primary flow 10 to 30 percent to a small UC.

(10) Rural areas: primary flow to a tract outside a UA or UC.

Based on this classification, and consistent with our current policy as set forth in the CY 2015 PFS final rule with comment period (79 FR 67745), we are proposing to continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the ambulance fee schedule. As discussed in the CY 2007 PFS final rule with comment period (71 FR 69715) and the CY 2015 PFS final rule with comment period (79 FR 67745), the Office of Rural Health Policy within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls in RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We refer readers to HRSA's Web site at *ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf* for additional information. Consistent with the HRSA guidelines discussed above and the policy we adopted in the CY 2015 PFS final rule with comment period (79 FR 67750), we are proposing for CY 2016 and subsequent CYs, to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country, and thus would be appropriate to apply for ambulance fee schedule payment purposes.

Also, consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67749), we would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We have determined that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. Also, payment under the ambulance fee schedule is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the ambulance fee schedule. Therefore, under the ambulance fee schedule, we would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people.

We invite public comments on our proposals, as discussed in this proposed rule, to continue to use the updated RUCA codes under the ambulance fee schedule for CY 2016 and subsequent CYs.

As we stated in the CY 2015 PFS proposed rule (79 FR 40374), the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport; thus, a transport is paid differently depending on whether the point of pick-up is in an urban or a rural area. During claims processing, a geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance

transport based on the point of pick-up ZIP code that is indicated on the claim.

The continued implementation of the revised OMB delineations and the updated RUCA codes would continue to affect whether or not transports would be eligible for rural adjustments under the ambulance fee schedule statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)).

Section 1834(l)(12) of the Act (as amended most recently by section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015) specifies that, for services furnished during the period July 1, 2004 through December 31, 2017, the payment amount for the ground ambulance base rate is increased by a ''percent increase'' (Super Rural Bonus) where the ambulance transport originates in a ''qualified rural area,'' which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a ''super rural area''). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). As discussed in section III.A.2.b. of this proposed rule, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. As we stated in the CY 2015 PFS proposed rule (79 FR 40374) and final rule with comment period (79 FR 67746), adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. Furthermore, under section 1834(l)(13) of the Act (as amended most recently by section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015), for ground ambulance transports furnished through December 31, 2017, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)). As discussed in section III.A.2.a. of this proposed rule, we are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Similar to our discussion in the CY 2015 PFS proposed rule (79 FR 40374) and final rule with comment period (79 FR 67746), if we continue to use OMB's revised delineations and the updated RUCA codes for CY 2016 and subsequent CYs, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but were within urban areas under the geographic delineations in effect in CY 2014) would continue to experience increases in payment for such transports (as compared to the CY 2014 geographic delineations) because they may be eligible for the rural adjustment factors discussed above in this section. In addition, those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but were previously in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA under the geographic delineations in effect in CY 2014) would continue to experience decreases in payment for such transports (as compared to the CY 2014 geographic delineations) because they would no longer be eligible for the rural adjustment factors discussed above in this section.

The continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs would mean the continued recognition of urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. As discussed above in this section, we are proposing to continue to use the updated RUCA codes to identify rural census tracts within MSAs, such that any census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas. In order to determine which ZIP codes are included in each such rural census tract, we are proposing to continue to use the ZIP code approximation file developed by HRSA. This file includes the 2010 RUCA code designation for each ZIP code and can be found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. If ZIP codes are added over time to the USPS ZIP code file (and thus are not included in the 2010 ZIP code approximation file provided to us by HRSA) or if ZIP codes are revised over time, we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB Web sites, located at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx* and *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*.

Based on the April 2015 USPS ZIP code file that we are using in this proposed rule to assess the impacts of the revised geographic delineations, there are a total of 42,925 ZIP codes in the U.S. Table 16 sets forth an analysis of the number of ZIP codes that changed urban/rural status in each U.S. state and territory after CY 2014 due to our implementation of the revised OMB delineations and the updated RUCA codes beginning in CY 2015, using the April 2015 USPS ZIP code file, the revised OMB delineations, and the updated RUCA codes (including the RUCA ZIP code approximation file discussed above). Based on this data, the geographic designations for approximately 95.22 percent of ZIP codes are unchanged by OMB's revised delineations and the updated RUCA codes. Similar to the analysis set forth in the CY 2015 PFS final rule with comment period, as corrected (79 FR 78716 through 78719), as reflected in Table 16, more ZIP codes have changed from rural to urban (1,600 or 3.73 percent) than from urban to rural (451 or 1.05 percent). In general, it is expected that ambulance providers and suppliers in 451 ZIP codes within 42 states, may continue to experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. The state of Ohio has the most ZIP codes that changed from urban to rural with a total of 54, or 3.63 percent. Ambulance providers and suppliers in 1,600 ZIP codes within 44 states and Puerto Rico may continue to experience payment decreases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. The state of West Virginia has the most ZIP codes that changed from rural to urban (149 or 15.92 percent). As discussed above, these findings are illustrated in Table 16.

TABLE 16—ZIP CODE ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State/Territory*	Total ZIP codes	Total ZIP codes changed rural to urban	Percentage of total ZIP codes	Total ZIP codes changed urban to rural	Percentage of total ZIP codes	Total ZIP codes not changed	Percentage of total ZIP codes not changed
AK	276	0	0.00	0	0.00	276	100.00
AL	854	43	5.04	8	0.94	803	94.03
AR	725	19	2.62	9	1.24	697	96.14
AS	1	0	0.00	0	0.00	1	100.00
AZ	569	21	3.69	7	1.23	541	95.08
CA	2723	85	3.12	43	1.58	2595	95.30
CO	677	4	0.59	9	1.33	664	98.08
CT	445	37	8.31	0	0.00	408	91.69
DC	303	0	0.00	0	0.00	303	100.00
DE	99	6	6.06	0	0.00	93	93.94
EK	63	0	0.00	0	0.00	63	100.00
EM	857	35	4.08	4	0.47	818	95.45
FL	1513	69	4.56	9	0.59	1435	94.84
FM	4	0	0.00	0	0.00	4	100.00
GA	1032	47	4.55	4	0.39	981	95.06
GU	21	0	0.00	0	0.00	21	100.00
HI	143	9	6.29	3	2.10	131	91.61
IA	1080	20	1.85	3	0.28	1057	97.87
ID	335	0	0.00	0	0.00	335	100.00
IL	1629	68	4.17	7	0.43	1554	95.40
IN	1000	33	3.30	20	2.00	947	94.70
KY	1030	30	2.91	5	0.49	995	96.60
LA	739	69	9.34	1	0.14	669	90.53
MA	751	8	1.07	9	1.20	734	97.74
MD	630	69	10.95	0	0.00	561	89.05
ME	505	5	0.99	12	2.38	488	96.63
MH	2	0	0.00	0	0.00	2	100.00
MI	1185	22	1.86	21	1.77	1142	96.37
MN	1043	31	2.97	7	0.67	1005	96.36
MP	3	0	0.00	0	0.00	3	100.00
MS	541	14	2.59	1	0.18	526	97.23
MT	411	0	0.00	3	0.73	408	99.27
NC	1102	87	7.89	10	0.91	1005	91.20
ND	419	2	0.48	0	0.00	417	99.52
NE	632	7	1.11	6	0.95	619	97.94
NH	292	0	0.00	2	0.68	290	99.32
NJ	748	1	0.13	2	0.27	745	99.60
NM	438	4	0.91	2	0.46	432	98.63
NV	257	1	0.39	2	0.78	254	98.83
NY	2246	84	3.74	42	1.87	2120	94.39
OH	1487	23	1.55	54	3.63	1410	94.82
OK	791	5	0.63	7	0.88	779	98.48
OR	496	26	5.24	9	1.81	461	92.94
PA	2244	129	5.75	38	1.69	2077	92.56
PR	177	21	11.86	0	0.00	156	88.14
PW	2	0	0.00	0	0.00	2	100.00
RI	91	2	2.20	1	1.10	88	96.70
SC	544	47	8.64	2	0.37	495	90.99
SD	418	0	0.00	1	0.24	417	99.76
TN	814	52	6.39	12	1.47	750	92.14
TX	2726	64	2.35	32	1.17	2630	96.48
UT	360	2	0.56	0	0.00	358	99.44
VA	1277	98	7.67	19	1.49	1160	90.84
VI	16	0	0.00	0	0.00	16	100.00
VT	309	3	0.97	0	0.00	306	99.03
WA	744	17	2.28	6	0.81	721	96.91
WI	919	19	2.07	5	0.54	895	97.39
WK	711	11	1.55	7	0.98	693	97.47
WM	342	2	0.58	3	0.88	337	98.54
WV	936	149	15.92	3	0.32	784	83.76
WY	198	0	0.00	1	0.51	197	99.49
TOTALS	42,925	1600	3.73	451	1.05	40,874	95.22

*ZIP code analysis includes U.S. States and Territories (FM—Federated States of Micronesia, GU—Guam, MH—Marshall Islands, MP—Northern Mariana Islands, PW—Palau, AS—American Samoa; VI—Virgin Islands; PR—Puerto Rico). Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs): EM—East Missouri, WM—West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK) and the rest of the state is West Kansas (WK).

For more detail on the impact of our proposals, in addition to Table 16, the following files are available through the Internet on the Ambulance Fee Schedule Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html:* ZIP Codes By State Changed From Urban To Rural: ZIP Codes By State Changed From Rural To Urban: List of ZIP Codes With RUCA Code Designations: and Complete List of ZIP Codes.

As discussed in the CY 2015 PFS final rule with comment period (79 FR 67750), we believe the most current OMB statistical area delineations, coupled with the updated RUCA codes, more accurately reflect the contemporary urban and rural nature of areas across the country, and thus we believe the use of the most current OMB delineations and RUCA codes under the ambulance fee schedule will enhance the accuracy of ambulance fee schedule payments. As we discussed in the CY 2015 PFS final rule with comment period (79 FR 67750), we considered, as alternatives, whether it would be appropriate to delay the implementation of the revised OMB delineations and the updated RUCA codes, or to phase in the implementation of the new geographic delineations over a transition period for those ZIP codes losing rural status. We determined that it would not be appropriate to implement a delay or a transition period for the revised geographic delineations for the reasons set forth in the CY 2015 PFS final rule. Similarly, we considered whether a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. We continue to believe that it is important to use the most current OMB delineations and RUCA codes available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts. Because we believe the revised OMB delineations and updated RUCA codes more accurately identify urban and rural areas and enhance the accuracy of the Medicare ambulance fee schedule, we do not believe a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. Areas that have lost their rural status and become urban have become urban because of recent population shifts. We believe it is important to base payment on the most accurate and up-to-date geographic area delineations available. Furthermore, we believe a delay in implementation of the revised OMB delineations and the updated RUCA codes would be a disadvantage to the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes. Thus, we are not proposing a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs.

We invite public comments on our proposals to continue implementation of the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee schedule. In addition, we invite public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.

4. Proposed Changes to the Ambulance Staffing Requirement

Under section 1861(s)(7) of the Act, Medicare Part B covers ambulance services when the use of other methods of transportation is contraindicated by the individual's medical condition, but only to the extent provided in regulations. Section 410.41(b)(1) requires that a vehicle furnishing ambulance services at the Basic Life Support (BLS) level must be staffed by at least two people, one of whom must meet the following requirements: (1) be certified as an emergency medical technician by the state or local authority where the services are furnished, and (2) be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

Section 410.41(b)(2) states that, for vehicles furnishing ambulance services at the Advanced Life Support (ALS) level, ambulance providers and suppliers must meet the staffing requirements for vehicles furnishing services at the BLS level. In addition, one of the two staff members must be certified as a paramedic or an emergency medical technician, by the state or local authority where the services are being furnished, to perform one or more ALS services. These staffing requirements are further explained in the Medicare Benefit Policy Manual (Pub. No. 100–02), Chapter 10 (see sections 10.1.2 and 30.1.1)

In its July 24, 2014 Management Implication Report, 13–0006, entitled ''Medicare Requirements for Ambulance Crew Certification,'' the Office of Inspector General (OIG) discussed its investigation of ambulance suppliers in a state that requires a higher level of training than Medicare requires for ambulance staff. In some instances, OIG found that second crew members: (1) possessed a lower level of training than required by state law, or (2) had purchased or falsified documentation to establish their credentials. The OIG expressed its concern that our current regulations and manual provisions do not set forth licensure or certification requirements for the second crew member. The OIG was informed by federal prosecutors that prosecuting individuals who had purchased or falsified documentation to establish their credentials would be difficult because Medicare had no requirements regarding the second ambulance staff member and the ambulance transports complied with the relevant Medicare regulations and manual provisions for ambulance staffing.

The OIG recommended that Medicare revise its regulations and manual provisions related to ambulance staffing to parallel the standard used for vehicle requirements at § 410.41(a), which requires that ambulances be equipped in ways that comply with state and local laws. Specifically, the OIG recommended that our regulation and manual provisions addressing ambulance vehicle staffing should indicate that, for Medicare to cover ambulance services furnished to a Medicare beneficiary, the ambulance crew must meet the requirements currently set forth in § 410.41(b) or the state and local requirements, whichever are more stringent. Currently, § 410.41(b) does not require that ambulance vehicle staff comply with all applicable state and local laws. We agree with OIG's concerns and believe that requiring ambulance staff to also comply with state and local requirements would enhance the quality and safety of ambulance services furnished to Medicare beneficiaries.

Accordingly, we are proposing to revise § 410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished, and the current Medicare requirements under § 410.41(b). We believe that this would, in effect, require both of the required ambulance vehicle staff to also satisfy any applicable state and local requirements that may be more stringent than those currently set forth at § 410.41(b), consistent with OIG's recommendation. In addition, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to include the proposed revised staffing requirements discussed above for

§ 410.41(b). These proposed revisions to § 410.41(b) and § 414.605 would account for differences in individual state or local staffing and licensure requirements, better accommodating state or local laws enacted to ensure beneficiaries' health and safety. Likewise, these proposed revisions would strengthen the federal government's ability to prosecute violations associated with such requirements and recover inappropriately or fraudulently received funds from ambulance companies found to be operating in violation of state or local laws. Furthermore, as discussed above, we believe that these proposals would enhance the quality and safety of ambulance services provided to Medicare beneficiaries.

In addition, we are proposing to revise § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified at a minimum as an emergency medical technician-basic (EMT-Basic), which we believe would more clearly state our current policy. Currently, these regulations require that, for BLS vehicles, one staff member be certified as an EMT (§ 410.41(b)) or EMT-Basic (§ 414.605). These proposed revisions to the regulations do not change our current policy, but clarify that one of the BLS vehicle staff members must be certified at the minimum level of EMT-Basic, but may also be certified at a higher level, for example, EMT-intermediate or EMT paramedic.

Finally, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions. This sentence (''For example, only in some states is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line''), has been included in the definition of BLS since the ambulance fee schedule was finalized in 2002 (67 FR 9100, Feb. 27, 2002). Because state laws may change over the course of time, we are concerned that this sentence may not accurately reflect the status of the relevant state laws over time. Therefore, we are proposing to delete the last sentence of this definition. Furthermore, we do not believe that the examples set forth in this sentence are necessary to convey the definition of BLS for Medicare coverage and payment purposes.

We invite public comments on our proposals to revise the ambulance vehicle staffing requirements in § 410.41(b) and § 414.605 as discussed above. If we finalize these proposals, we will revise our manual provisions addressing ambulance vehicle staffing as appropriate, consistent with our finalized policy.

B. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Primary Care and Care Coordination

Over the last several years, we have been increasing our focus on primary care, and have explored ways in which care coordination can improve health outcomes and reduce expenditures.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794, and 42917 through 42920), and the CY 2012 PFS final rule (76 FR 73063 through 73064), we discussed how primary care services have evolved to focus on preventing and managing chronic disease, and how refinements for payment for post-discharge care management services could improve care management for a beneficiary's transition from the hospital to the community setting. We acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved in primary care and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay. We initiated a public discussion on primary care and care coordination services, and stated that we would consider payment enhancements in future rulemaking as part of a multiple year strategy exploring the best means to encourage primary care and care coordination services.

In the CY 2013 PFS proposed rule (77 FR 44774 through 44775), we noted several initiatives and programs designed to improve payment for, and encourage long-term investment in, care management services. These include the Medicare Shared Savings Program; testing of the Pioneer Accountable Care Organization (ACO) and the Advance Payment ACO model; the Primary Care Incentive Payment (PCIP) Program; the patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration; the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration; the Comprehensive Primary Care (CPC) initiative; and the HHS Strategic Framework on Multiple Chronic Conditions. We also noted that we were monitoring the progress of the AMA Chronic Care Coordination Workgroup in developing codes to describe care transition and care coordination activities, and proposed refinement of the PFS payment for post discharge care management services.

In the CY 2013 PFS final rule (77 FR 68978 through 68994), we finalized policies for payment of Transitional Care Management (TCM) services, effective January 1, 2013. We adopted two CPT codes (99495 and 99496) to report physician or qualifying nonphysician practitioner care management services for a patient following a discharge from an inpatient hospital or SNF, an outpatient hospital stay for observation or partial hospitalization services, or partial hospitalization in a community mental health center. As a condition for receiving TCM payment, a face-to-face visit was required.

In the CY 2014 PFS proposed rule (78 FR 43337 through 43343), we proposed to establish separate payment under the PFS for chronic care management (CCM) services and proposed a scope of services and requirements for billing and supervision. In the CY 2014 PFS final rule (78 74414 through 74427), we finalized policies to establish separate payment under the PFS for CCM services furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. In the CY 2015 PFS final rule (79 FR 67715 through 67730), additional billing requirements were finalized, including the requirement to furnish CCM services using a certified electronic health record or other electronic technology. Payment for CCM services was effective beginning on January 1, 2015, for physicians billing under the PFS.

b. RHC and FQHC Payment Methodologies

A RHC or FQHC visit must be a face-to-face encounter between the patient and a RHC or FQHC practitioner (physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker, and under certain conditions, an RN or LPN furnishing care to a homebound RHC or FQHC patient) during which time one or more RHC or FQHC services are furnished. A TCM service can also be a RHC or FQHC visit. A Diabetes Self-Management Training

(DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be a FQHC visit.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary medical and mental health services, and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B MAC calculates the AIR for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for those RHCs that have an exception to the payment limit. Services furnished incident to a RHC professional service are included in the per-visit payment and are not billed separately.

FQHCs have also been paid under the AIR methodology; however, on October 1, 2014, FQHCs began to transition to a FQHC PPS system in which they are paid based on the lesser of a national encounter-based rate or their total adjusted charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC geographic adjustment factor. It is also increased by 34 percent when a FQHC furnishes care to a patient that is new to the FQHC or to a beneficiary receiving an Initial Preventive Physical Examination (IPPE) or an Annual Wellness Visit (AWV). Both the AIR and FQHC PPS payment rates were designed to reflect all the services that a RHC or FQHC furnishes in a single day, regardless of the length or complexity of the visit or the number or type of practitioners seen.

c. Payment for CCM Services

To address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for CCM services under CPT code 99490 when CCM service requirements are met.

RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. While many RHCs and FQHCs coordinate services within their own facilities, and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are not included in the RHC or FQHC payment. This proposed rule proposes to provide an additional payment for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payment, beginning on January 1, 2016. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

d. Solicitation of Comments on Payment for CCM Services in RHCs and FQHCs

In the May 2, 2014 ''Medicare Program: Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral; Final Rule'' (79 FR 25447), we discussed ways to achieve the Affordable Care Act goal of furnishing integrated and coordinated services, and specifically noted the CCM services program beginning in 2015 for physicians billing under the PFS. We encouraged RHCs and FQHCs to review the CCM services information in the CY 2014 PFS final rule with comment period and submit comments to us on how the CCM services payment could be adapted for RHCs and FQHCs to promote integrated and coordinated care in RHCs and FQHCs.

All of the comments we received in response to this request were strongly supportive of payment to RHCs and FQHCs for CCM services. Some commenters were concerned that the requirements for electronic exchange of information and interoperability with other providers would be difficult for some entities, and that some patients do not have the resources to receive secure messages via the internet. One commenter suggested that the additional G-codes for CCM services should be sufficient to cover the associated costs of documenting care coordination in FQHCs, and another commenter suggested that we develop a risk-adjusted CCM services fee. We also received subsequent recommendations from the National Association of Rural Health Clinics on various payment options for CCM services in RHCs. These comments were very helpful in forming the basis for this proposal, and we thank the commenters for their comments.

2. Proposed Payment Methodology and Billing for CCM Services in RHCs and FQHCs

a. Proposed Payment Methodology and Billing Requirements

The requirements we are proposing for RHCs and FQHCs to receive payment for CCM services are consistent with those finalized in the CY 2015 PFS final rule with comment period for practitioners billing under the PFS and are summarized in Table 17. We propose to establish payment, beginning on January 1, 2016, for RHCs and FQHCs who 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 place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The CPT code descriptor sets forth the eligibility guidelines for CCM services and will serve as the basis for potential medical review. In accordance with both the CPT instructions and Medicare policy, only one practitioner can bill this code per month, and there are restrictions regarding the billing of other overlapping care management services during the same service period. The following section discusses these aspects of our proposal in more detail and additional information will be communicated in subregulatory guidance.

We propose that a RHC or FQHC can bill for CCM services furnished by, or incident to, a RHC or FQHC physician, nurse practitioner, physician assistant, or certified nurse midwife for a RHC or FQHC patient once per month, and that only one CCM payment per beneficiary per month can be paid. If another practice furnishes CCM services to a beneficiary, the RHC or FQHC cannot bill for CCM services for the same beneficiary for the same service period. We also propose that TCM and any other program that provides additional payment for care management services (outside of the RHC AIR or FQHC PPS payment) cannot be billed during the same service period.

For purposes of meeting the minimum 20-minute requirement, the RHC or FQHC could count the time of only one practitioner or auxiliary staff (for example, a nurse, medical assistant, or

other individual working under the supervision of a RHC or FQHC physician or other practitioner) at a time, and could not count overlapping intervals such as when two or more RHC or FQHC practitioners are meeting about the patient. Only conversations that fall under the scope of CCM services would be included towards the time requirement.

We noted that for billing under the PFS, the care coordination included in services such as office visits do not always describe adequately the non-face-to-face care management work involved in primary care. We also noted that payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or SNF stay. In considering CCM payment for RHCs and FQHCs, we believe that the non-face-to-face time required to coordinate care is also not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique services that are required in order to furnish CCM services that are not already captured in the RHC AIR or the FQHC PPS payment.

We propose that payment for CCM services be based on the 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. (For the first quarter of 2015, the national average payment rate is $42.91 per beneficiary per calendar month.) CCM payment to RHCs and FQHCs would be based on the PFS amount, but would be paid as part of the RHC and FQHC benefit, using the CPT code to identify that the requirements for payment are met and a separate payment should be made. We also propose to waive the RHC and FQHC face-to-face requirements when CCM services are furnished to a RHC or FQHC patient. Coinsurance would be applied as applicable to FQHC claims, and coinsurance and deductibles would apply as applicable to RHC claims. RHCs and FQHCs would continue to be required to meet the RHC and FQHC Conditions of Participation and any additional RHC or FQHC payment requirements. We intend to provide detailed billing instructions in subregulatory guidance following publication of a final rule.

b. Other Options Considered

We considered adding CCM services as a RHC or FQHC covered stand-alone service and removing the RHC/FQHC policy requiring a face-to-face visit requirement for this service. Under this option, payment for RHCs would be at the AIR, payment for FQHCs would be the lesser of total charges or the PPS rate, and if CCM services are furnished on the same day as another payable medical visit, only one visit would be paid. We are not proposing this payment option because it would result in a significant overpayment if no other services were furnished on the same day, and would result in no additional payment if furnished on the same day as another medical visit.

We also considered allowing RHCs and FQHCs to carve out CCM services and bill them separately to the PFS. We are not proposing this payment option because CCM services are a RHC and FQHC service and only non-RHC/FQHC services can be billed through the PFS.

We also considered developing a modifier that could be added to the claim for additional payment when CCM services are furnished. We are not proposing this option because it would require that payment for CCM services be made only when furnished along with a billable service that qualifies as an RHC or FQHC service.

We also considered establishing payment for CCM costs on a reasonable cost basis though the cost report. We are not proposing this option because payment for CCM services through the cost report would complicate coinsurance and/or deductible accountability, whereas it is more administratively feasible to apply coinsurance and/or deductible on a RHC/FQHC claim, as applicable. For example, section 1833(a)(3) of the Act specifies that influenza and pneumococcal vaccines and their administration are exempt from payment at 80 percent of reasonable costs and payment to RHCs and FQHCs for such services is at 100 percent of reasonable cost. Since influenza and pneumococcal vaccines and their administration are not subject to copayment, it is administratively feasible to pay these services through the cost report.

3. Proposed Requirements for CCM Payment in RHCs and FQHCs

a. Proposed Beneficiary Eligibility for CCM Services

Consistent with beneficiary eligibility requirements under the PFS, we propose that RHCs and FQHCs receive payment for furnishing CCM services to patients with multiple chronic conditions that are expected to survive at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. RHCs and FQHCs are encouraged to focus on patients with high acuity and high risk when furnishing CCM services to eligible patients, including those who are returning to a community setting following discharge from a hospital or SNF.

b. Proposed Beneficiary Agreement Requirements

Not all patients who are eligible for separately payable CCM services may necessarily want these services to be provided, and some patients who receive CCM services may wish to discontinue them. A beneficiary who declines to receive CCM services from the RHC or FQHC, or who accepts the services and then chooses to revoke his/her agreement, would continue to be able to receive care from the RHC or FQHC and receive any care management services that are currently being furnished under the RHC AIR or FQHC PPS payment system.

Consistent with beneficiary notification and consent requirements under the PFS, we propose that the following requirements be met before the RHC or FQHC can furnish or bill for CCM services:

- The eligible beneficiary must be informed about the availability of CCM services from the RHC or FQHC and provide his or her written agreement to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what CCM services are, how they differ from any care management services the RHC or FQHC currently offers, how these services are accessed, how the patient's information will be shared among others, that a non RHC or FQHC cannot furnish or bill for CCM services during the same calendar month that the RHC or FQHC furnishes CCM services, the applicability of coinsurance even when CCM services are not delivered face-to-face in the RHC or FQHC, and that any care management services that are currently provided will continue even if the patient does not agree to have CCM services provided.
- The RHC or FQHC must document in the patient's medical record that all of the CCM services were explained and offered to the patient, and note the patient's decision to accept these services.

• At the time the agreement is obtained, the eligible beneficiary must be informed that the agreement for CCM services could be revoked by the beneficiary at any time either verbally or in writing, and the RHC or FQHC practitioner must explain the effect of a revocation of the agreement for CCM services. If the revocation occurs during a CCM 30-day period, the revocation would be effective at the end of that period. The eligible beneficiary must also be informed that the RHC or FQHC is able to be separately paid for these services during the 30-day period only if no other practitioner or eligible entity, including another RHC or FQHC that is not part of the RHC's or FQHC's organization, has already billed for this service. Since only one CCM payment can be paid per beneficiary per month, the RHC or FQHC would need to ask the patient if they are already receiving CCM services from another practitioner. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the RHC or FQHC would not be providing CCM services beyond the current 30-day period. A beneficiary who has revoked the agreement for CCM services from a RHC or FQHC may choose instead to receive these services from a different practitioner (including another RHC or FQHC), beginning at the conclusion of the 30-day period.

• The RHC or FQHC must provide a written or electronic copy of the care plan to the beneficiary and record this in the beneficiary's electronic medical record.

c. Proposed Scope of CCM Services in RHCs and FQHCs

We propose that all of the following scope of service requirements must be met to bill for CCM services:

• Initiation of CCM services during a comprehensive Evaluation/Management (E/M), AWV, or IPPE visit. The time spent furnishing these services would not be included in the 20 minute monthly minimum required for CCM billing.

• Continuity of care with a designated RHC or FQHC practitioner with whom the patient is able to get successive routine appointments.

• Care management for chronic conditions, including systematic assessment of a patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications.

• A patient-centered plan of care document created by the RHC or FQHC practitioner furnishing CCM services in consultation with the patient, caregiver, and other key practitioners treating the patient to assure that care is provided in a way that is congruent with patient choices and values. The plan would be a comprehensive plan of care for all health issues based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It would typically include, but not be limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. A complete list of problems, medications, and medication allergies would be in the electronic health record to inform the care plan, care coordination, and ongoing clinical care.

• Creation of an electronic care plan that would be available 24 hours a day and 7 days a week to all practitioners within the RHC or FQHC who are furnishing CCM services whose time counts towards the time requirement for billing the CCM code, and to other practitioners and providers, as appropriate, who are furnishing care to the beneficiary, to address a patient's urgent chronic care needs. No specific electronic solution or format is required to meet this scope of service element. However, we encourage RHCs and FQHCs who wish to learn more about currently available electronic standards for care planning to refer to the proposed rulemaking for the 2015 Edition of Health Information Technology Certification Criteria, which includes a proposal to enable users of certified health IT to create and receive care plan information in accordance with the C–CDA Release 2.0 standard (80 FR 16842).

• Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and SNFs. The RHC or FQHC must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The RHC or FQHC must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way to reduce the need for repeat visits to emergency departments and readmissions to hospitals and SNFs.

• Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in the RHC's or FQHC's medical record system.

• Secure messaging, internet or other asynchronous non-face-to-face consultation methods for a patient and caregiver to communicate with the provider regarding the patient's care in addition to the use of the telephone. We would note that the faxing of information would not meet this requirement. These methods would be required to be available, but would not be required to be used by every practitioner or for every patient receiving CCM services.

d. Proposed Electronic Health Records (EHR) Requirements

We believe that the use of EHR technology that allows data sharing is necessary to assure that RHCs and FQHCs can effectively coordinate services with other practitioners for patients with multiple chronic conditions. Therefore, we propose the following requirements:

• Certified health IT must be used for the recording of demographic information, health-related problems, medications, and medication allergies; a clinical summary record; and other scope of service requirements that reference a health or medical record.

• RHCs and FQHCs must use technology certified to the edition(s) of certification criteria that is, at a minimum, acceptable for the EHR Incentive Programs as of December 31st of the year preceding each CCM payment year to meet the following core technology capabilities: structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary. For example, technology used to furnish CCM services beginning on January 1, 2016, would be required to meet, at a minimum, the requirements included in the 2014 Edition certification criteria. For the purposes of the scope of services, we refer to technology meeting these requirements as ''CCM Certified Technology.''

• Applicable HIPAA standards would apply to electronic sharing of patient information.

TABLE 17—SUMMARY OF PROPOSED CCM SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS

CCM Scope of service/billing requirements	Health IT requirements
Initiation of CCM services at an AWV, IPPE, or a comprehensive E/M visi.	None.
Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record. 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 demographics, problems, medications, medication allergies, and creation of structured clinical summary records using CCM certified technology.
Access to CCM services 24/7 (providing the beneficiary with a means to make timely contact with the RHC or FQHC to address his or her urgent chronic care needs regardless of the time of day or day of the week.	None.
Continuity of care with a designated RHC or FQHC practitioner with whom the beneficiary is able to get successive routine appointment.	None.
CCM services 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 medication.	None.
Creation of a 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. Share the care plan as appropriate with other practitioners and providers.	Must at least electronically capture care plan information; make this information 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 for CCM services; and share care plan information electronically (other than by fax) as appropriate with other practitioners, providers, and caregivers.
Provide the beneficiary with a written or electronic copy of the care plan and document its provision in the electronic medical record.	Document provision of the care plan as required to the beneficiary in the EHR using CCM certified technology.
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 CCM certified technology. Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (other than by fax).
Coordination with home and community based clinical service providers	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 CCM certified technology.
Enhanced opportunities for the beneficiary and any caregiver to communicate with the RHC or FQHC 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.	None.
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.	
Document in the beneficiary's medical record that all of the CCM services were explained and offered, and note the beneficiary's decision to accept or decline these services.	
Document the beneficiary's written consent and authorization in the EHR using CCM certified technology.	Document the beneficiary's written consent and authorization in the EHR using CCM certified technology.
Beneficiary consent—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.	None.
Beneficiary consent—Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month.	None.

We invite public comments on all aspects of the proposed payment methodology and billing for CCM services in RHCs and FQHCs, the proposed CCM requirements for RHCs and FQHCs, and any other aspect of our proposal.

C. Healthcare Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

1. RHC Payment Methodology and Billing Requirements

RHCs are paid an all-inclusive rate (AIR) per visit for medically necessary primary health services and qualified preventive health services furnished face-to-face by a RHC practitioner to a Medicare beneficiary. The all-inclusive payment system was designed to minimize reporting requirements, and as such, the rate includes all costs associated with the services that a RHC furnishes in a single day to a Medicare

beneficiary, regardless of the length or complexity of the visit or the number or type of RHC practitioners seen. Except for certain preventive services that are not subject to coinsurance requirements, it has not been necessary for RHCs to submit reporting of medical and procedure codes, such as level I and level II of the HCPCS, on claims for services that were furnished during the visit to determine Medicare payment. Generally, the services reported using the appropriate site of service revenue code on a RHC claim receives payment under the AIR, with coinsurance and deductible applied based upon the associated charges on that line, notwithstanding other Medicare requirements.

Historically, billing instructions for RHCs and Federally Qualified Health Centers (FQHCs) have been similar. Beginning on April 1, 2005, through December 31, 2010, RHCs and FQHCs were no longer required to report HCPCS when billing for RHC and FQHC services rendered during an encounter, absent a few exceptions. CMS Transmittal 371, dated November 19, 2004, eliminated HCPCS coding for FQHCs and eliminated the additional line item reporting of preventive services for RHCs and FQHCs for claims with dates of service on or after April 1, 2005. CMS Transmittal 1719, dated April 24, 2009, effective October 1, 2009, required RHCs and FQHCs to report HCPCS codes for a few services, such as certain preventive services eligible for a waiver of deductible, services subject to frequency limits, and services eligible for payments in addition to the all-inclusive rate.

Section 1834(o)(1)(B) of the Act, as added by the Affordable Care Act, required that FQHCs begin reporting services using HCPCS codes to develop and implement the FQHC PPS. Since January 1, 2011, FQHCs have been required to report all services furnished during an encounter by specifically listing the appropriate HCPCS code(s) for each line item, along with the site of service revenue code(s), when billing Medicare. As of October 1, 2014, HCPCS coding is used to calculate payment for FQHCs that are paid under the FQHC PPS.

Section 4104 of the Affordable Care Act waived the coinsurance and deductible for the initial preventive physical examination (IPPE), the annual wellness visit (AWV), and other Medicare covered preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Since January 1, 2011, HCPCS coding has been required for these preventive services when reported by RHCs. When billing for an approved preventive service, RHCs must report an additional line with the appropriate site of service revenue code with the approved preventive service HCPCS code and the associated charges. Although HCPCS coding is currently required for approved preventive services on RHC claims, HCPCS coding is not used to determine RHC payment.

2. Proposed Requirement for Reporting of HCPCS Coding for All Services Furnished by RHCs During a Medicare Visit

For payment under Medicare Part B, the statute requires health transactions to be exchanged electronically, subject to certain exceptions, using standards specified by the Secretary. Specifically, section 1862(a)(22) of the Act requires that no payment may be made under part A or part B for any expenses incurred for items or services, subject to exceptions under section 1862(h), for which a claim is submitted other than in an electronic form specified by the Secretary. Further, section 1173 of the Act, added by section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for transactions. These include but are not limited to health claims or equivalent encounter information. As a result of the HIPAA amendments, HHS adopted regulations pertaining to data standards for health care related transactions. The regulations at 45 CFR 160.103 define a covered entity to include a provider of medical or health services (as defined in section 1861(s) of the Act), and define the types of standard transactions. When conducting a transaction, under 45 CFR 162.1000, a covered entity must use the applicable medical data code sets described in § 162.1002 that are valid at the time the health care is furnished, and these regulations define the standard medical data code sets adopted by the Secretary as HCPCS and CPT (Current Procedural Terminology–Fourth Edition) for physician services and other health care services.

Under section 1861(s)(2)(E) of the Act, a RHC is a supplier of ''medical or health services.'' As such, our regulations require these covered entities to report a standard medical code set for electronic health care transactions, although our program instructions have directed RHCs to submit HCPCS codes only for preventive services. We believe reporting of HCPCS coding for all services furnished by a RHC would be consistent with the health transactions requirements, and would provide useful information on RHC patient characteristics, such as level of acuity and frequency of services furnished, and the types of services being furnished by RHCs. This information would also allow greater oversight of the program and inform policy decisions.

We propose that all RHCs must report all services furnished during an encounter using standardized coding systems, such as level I and level II of the HCPCS, for dates of service on or after January 1, 2016. In accordance with section 1862(h) of the Act, in limited situations RHCs that are unable to submit electronic claims and RHCs with fewer than 10 full time equivalent employees are exempt from submitting claims electronically. We propose that RHCs exempt from electronic reporting under 1862(h) of the Act must also report all services furnished during an encounter using HCPCS coding via paper claims for dates of services on or after January 1, 2016. This proposal would necessitate new billing practices for such RHCs, but we believe there would be no significant burden for the limited number of RHCs exempt from electronic billing.

Under this proposal, a HCPCS code would be reported along with the presently required Medicare revenue code for each service furnished by the RHC to a Medicare patient. Although HCPCS coding is currently used to determine FQHC payment under the FQHC PPS, under this proposal, RHCs would continue to be paid under the AIR and there would be no change in their payment methodology.

Accordingly, we are proposing to remove the requirement at § 405.2467(b) pertaining to HCPCS coding for FQHCs and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively. We are also proposing to add a new paragraph (g)(3) to § 405.2462 to require FQHCs and RHCs, whether or not exempt from electronic reporting under § 424.32(d)(3), to report on Medicare claims all service(s) furnished during each FQHC and RHC visit (as defined in § 405.2463) using HCPCS and other codes as required.

We propose to require reporting of HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. We are aware that many RHCs already record this information through their billing software or electronic health record systems; however, we recognize there may be some RHCs that need to make

changes in their systems. We invite RHCs to submit comments on the feasibility of updating their billing systems to meet this implementation date of January 1, 2016.

As part of the implementation of the HCPCS coding requirement, we plan to provide instructions on how RHCs are to report HCPCS and other coding and clarify other appropriate billing procedures through program instruction. CMS' Medicare claims processing system would be revised to accept the addition of the new RHC reporting requirements effective January 1, 2016.

D. Payment to Grandfathered Tribal FQHCs That Were Provider-Based Clinics on or Before April 7, 2000

1. Background

a. Health Services to American Indians and Alaskan Natives (AI/AN)

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S.

In 1976, the Indian Health Care Improvement Act (IHCIA, P.L. 94–437) amended the statute to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services to AI/ANs may be furnished by IHS operated facilities and programs and tribally-operated facilities and programs under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA, P.L 93–638).

According to the IHS Year 2015 Profile, the IHS healthcare delivery system currently consists of 46 hospitals, with 28 of those hospitals operated by the IHS and 18 of them operated by tribes under the ISDEAA.

Payment rates for inpatient and outpatient medical care furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service (PHS) Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (IHCIA) (25 U.S.C. 1601 et seq.), based on the previous year's cost reports from federal and tribal hospitals. The 1976 IHCIA provided the authority for CMS (then HCFA) to pay IHS for its hospital services to Medicare eligible patients, and in 1978 CMS agreed to use a Medicare all-inclusive payment rate for IHS hospitals and IHS hospital-based clinics.

There is an outpatient visit rate for Medicare visits in Alaska and an outpatient visit rate for Medicare visits in the lower 48 States. The Medicare outpatient rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(a), or a ''grandfathered'' facility as described at § 413.65(m). For calendar year 2015, the Medicare outpatient encounter rate is $564 for Alaska and $307 for the rest of the country (80 FR 18639, April 7, 2015).

b. Provider-Based Entities and the ''Grandfathering'' Provision

In 2000, we adopted regulations at § 413.65 that established criteria for facilities to be considered provider-based to a hospital for Medicare payment purposes. The provider-based rules apply to facilities located both on and off the main hospital campus for which provider-based status is sought.

In the CY 2001 Hospital Outpatient PPS final rule with comment period (65 FR 18507), we addressed comments on the proposed provider-based rules. In regard to IHS facilities, commenters expressed concern that the proposed rule would undermine the ISDEAA contracting and compacting relationships between the IHS and tribes because provider-based clinics must be clinically and administratively integrated into the hospital, and a tribe that assumes the operation of a provider-based clinic but not the operation of the hospital would not be able to meet this requirement. They were also concerned that the proposed proximity requirements would threaten the status of many IHS and tribal facilities that frequently were located in distant remote areas.

In response to these comments and the special provisions of law referenced above governing health care for IHS and the tribes, we recognized the special relationship between tribes and the United States government, and did not apply the general provider-based criteria to IHS and tribally-operated facilities. The regulations currently include a grandfathering provision at § 413.65(m) for IHS and tribal facilities that were provider-based to a hospital on or prior to April 7, 2000. This section states that facilities and organizations operated by the IHS or tribes will be considered to be departments of hospitals operated by the IHS or tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the IHS or a tribe and they are:

- Owned and operated by the IHS;
- Owned by the tribe but leased from the tribe by the IHS under the ISDEAA in accordance with applicable regulations and policies of the IHS in consultation with tribes; or
- Owned by the IHS but leased and operated by the tribe under the ISDEAA in accordance with applicable regulations and policies of the IHS in consultation with tribes.

Under the authority of the ISDEAA, a tribe may assume control of an IHS hospital and the provider-based clinics affiliated with the hospital, or may only assume responsibility of the provider-based clinic. On August 11, 2003, we issued a letter to Trailblazer Health Enterprises, LLC, stating that changes in the status of a hospital or facility from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital, would not affect the facility's grandfathered status if the resulting configuration is one which would have qualified for grandfathering under § 413.65(m) if it had been in effect on April 7, 2000.

The Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at § 482.12 require administrative and clinical integration between a hospital and its clinics, departments, and provider-based entities. A tribal clinic billing under an IHS hospital's CMS Certification Number (CCN), without any additional administrative or clinical relationship with the IHS hospital, could put that hospital at risk for non-compliance with the CoPs.

Consequently, we believe that a different structure is needed to maintain access to care for AI/AN populations served by these hospitals and clinics, while also ensuring that these facilities are in compliance with our health and safety rules. The FQHC program may provide an alternative structure that meets the needs of these tribal clinics and the populations they serve, while also ensuring the IHS hospitals are not at risk for non-compliance with the requirements in § 482.12.

c. Federally Qualified Health Centers (FQHCs)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 and were effective beginning on October 1, 1991. They are facilities that furnish services

that are typically furnished in an outpatient clinic setting.

The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in section 1861(aa)(4) of the Act. All FQHCs are subject to Medicare regulations at 42 CFR part 405, subpart X, and 42 CFR part 491. Based on these provisions, the following three types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program grantees: Organizations receiving grants under section 330 of the PHS Act (42 U.S.C. 254b).
- Health Center Program ''look-alikes'': Organizations that have been identified by the Health Resources and Services Administration as meeting the requirements to receive a grant under section 330 of the PHS Act, but which do not receive section 330 grant funding.
- Outpatient health programs or facilities operated by a tribe or tribal organization under the ISDEAA, or by an urban Indian organization receiving funds under Title V of the IHCIA.

FQHCs are also entities that were treated by the Secretary for purposes of Medicare Part B as a comprehensive federally funded health center as of January 1, 1990 (see section 1861(aa)(4)(C) of the Act).

Section 1834 of the Act was amended by section 10501(i)(3)(A) of the Affordable Care Act by adding a new subsection (o), ''Development and Implementation of Prospective Payment System''. Section 1834(o)(1)(A) of the Act requires that the system include a process for appropriately describing the services furnished by FQHCs, and establish payment rates based on such descriptions of services, taking into account the type, intensity, and duration of services furnished by FQHCs. It also stated that the new system may include adjustments (such as geographic adjustments) as determined appropriate by the Secretary.

Section 1833(a)(1)(Z) was added by the Affordable Care Act to require that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the PPS amount determined under section 1834(o) of the Act.

In accordance with the requirements in the Affordable Care Act, beginning on October 1, 2014, payment to FQHCs is based on the lesser of the national encounter-based FQHC PPS rate, or the FQHC's total charges, for primary health services and qualified preventive health services furnished to Medicare beneficiaries. The FQHC PPS rate is adjusted by the FQHC geographic adjustment factor (GAF), which is based on the Geographic Practice Cost Index used under the PFS. The FQHC PPS rate is also adjusted when the FQHC furnishes services to a patient that is new to the FQHC, and when the FQHC furnishes an IPPE or an AWV. The FQHC PPS base rate for the period from October 1, 2014 to December 31, 2015 is $158.85. The rate will be adjusted in calendar year 2016 by the Medicare Economic Index (MEI), as defined at section 1842(i)(3) of the Act, and subsequently by either the MEI or a FQHC market basket (which would be determined pursuant to CMS regulations).

To assure that FQHCs receive appropriate payment for services furnished, we established a new set of five HCPCS G-codes for FQHCs to report Medicare visits. These G-codes include all the services in a typical bundle of services that would be furnished per diem to a Medicare patient at the FQHC. The five FQHC G-codes are:

G0466–FQHC visit, new patient
G0467–FQHC visit, established patient
G0468–FQHC visit, IPPE or AWV
G0469–FQHC visit, mental health, new patient
G0470–FQHC visit, mental health, established patient

FQHCs establish charges for the services they furnish to FQHC patients, including Medicare beneficiaries, and charges must be uniform for all patients, regardless of insurance status. The FQHC would determine the services that are included in each of the 5 FQHC G-codes, and the sum of the charges for each of the services associated with the G-code would be the G-code payment amount. Payment to the FQHC for a Medicare visit is the lesser of the FQHC's charges (as established by the G-code), or the PPS rate.

2. Proposed Payment Methodology and Requirements

We are proposing that IHS and tribal facilities and organizations that met the conditions of section 413.65(m) on or before April 7, 2000, and have a change in their status on or after April 7, 2000 from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the CoPs, may seek to become certified as grandfathered tribal FQHCs. To help avoid any confusion, we refer to these tribal FQHCs as grandfathered tribal FQHCs to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate of $158.85, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000.

Under the authority in 1834(o) of the Affordable Care Act to ''include adjustments . . . determined appropriate by the Secretary,'' we are proposing that these grandfathered tribal FQHCs be paid the lesser of their charges or a grandfathered tribal FQHC PPS rate of $307, which equals the Medicare outpatient per visit payment rate paid to them as a provider-based department, as set annually by the IHS, rather than the FQHC PPS per visit base rate of $158.85, and that coinsurance would be 20 percent of the lesser of the actual charge or the grandfathered tribal FQHC PPS rate. These grandfathered tribal FQHCs would be required to meet all FQHC certification and payment requirements. This FQHC PPS adjustment for grandfathered tribal clinics would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based as of April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally-operated hospital. This provision would also not apply in those instances where both the hospital and its provider-based clinic(s) are operated by the tribe or tribal organization.

Since we are proposing that these grandfathered tribal FQHCs would be paid based on the IHS payment rates and not the FQHC PPS payment rates, we are also proposing that the payment rate would not be adjusted by the FQHC PPS GAF, or be eligible for the special payment adjustments under the FQHC PPS for new patients, patients receiving an IPPE or an AWV. They would also not be eligible for the exceptions to the single per diem payment that is available to FQHCs paid under the FQHC PPS. As the IHS outpatient rate for Medicare is set annually, we also propose not to apply the MEI or a FQHC market basket adjustment that is applied annually to the FQHC PPS base rate. We are proposing that these adjustments not be applied because we believe that the special status of these grandfathered tribal clinics, and the enhanced payment they would receive under the FQHC PPS system, would make further adjustments unnecessary and/or duplicative of adjustments already made by IHS in deriving the rate. While we are proposing in this proposed rule an adjustment to the FQHC PPS rate to reflect the IHS rate for these grandfathered tribal clinics, if adopted as final, we will monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.

Grandfathered tribal FQHCs would be paid for services included in the FQHC benefit, even if those services are not included in the IHS Medicare outpatient all-inclusive rate. Services that are included in the IHS outpatient all-inclusive rate but not in the FQHC benefit would not be paid. Information on the FQHC benefit is available in Chapter 13 of the Medicare Benefit Policy Manual.

Grandfathered tribal FQHCs will be subject to Medicare regulations at part 405, subpart X, and part 491, except as noted in section III.D.2. of this proposed rule.

We therefore propose to revise § 405.2462, § 405.2463, § 405.2464, and § 405.2469 to specify the requirements for payment as a grandfathered tribal FQHC, and to specify payment provisions, adjustments, rates, and other requirements for grandfathered tribal FQHCs.

3. Transition

To become certified as a FQHC, an eligible tribe or tribal organization must submit a Form 855A and all required accompanied documentation, including an attestation of compliance with the Medicare FQHC Conditions for Coverage at part 491, to the Jurisdiction H Medicare Administrative Contractor (A/B MAC). After reviewing the application and determining that it is complete and approvable, the MAC would forward the application with its recommendation for approval to the CMS Regional Office (RO) that has responsibility for the geographic area in which the tribal clinic is located. The RO would issue a Medicare FQHC participation agreement to the tribal FQHC, including a CMS Certification Number (CCN), and would advise the MAC of the CCN number, to facilitate the MAC's processing of FQHC claims submitted by the tribal FQHC. Payment to grandfathered tribal FQHCs would begin on the first day of the month in the first quarter of the year subsequent to receipt of a Medicare CCN.

4. Conforming Changes

In addition, to the changes proposed in § 405.2462, § 405.2463, § 405.2464, and § 405.2469, we are proposing to: remove obsolete language from § 405.2410 regarding FQHCs that bill on the basis of the reasonable cost system, add a section heading to § 405.2415, and remove obsolete language from § 405.2448 regarding employment requirements.

E. Part B Drugs

1. Payment for Biosimilar Biological Products Under Section 1847A

Section 3139 of the Affordable Care Act amended section 1847A of the Act to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products using the average sale price (ASP) methodology.

Section 1847A(c)(6)(H) of the Act, as added by section 3139 of the Affordable Care Act, defines a biosimilar biological product as a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). Section 1847A(c)(6)(I) of the Act, as added by section 3139 of the Affordable Care Act, defines the reference biological product for a biosimilar biological product as the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

Section 3139 of the Affordable Care Act also amended section 1847A(b) of the Act by adding a new paragraph (8) to specify that the payment amount for a biosimilar biological product will be the sum of the following two amounts: the ASP as determined using the methodology described under paragraph 1847A(b)(6) applied to a biosimilar biological product for all National Drug Codes (NDCs) assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and 6 percent of the payment amount determined using the methodology in section 1847A(b)(4) of the Act for the corresponding reference biological product. The effective date for ASP statutory provisions on biosimilars was July 1, 2010. Separate sections of the Affordable Care Act also established a licensing pathway for biosimilar biological products.

To implement these provisions, we published CY 2011 PFS final rule with comment period (75 FR 73393 and 73394) in the **Federal Register** on November 29, 2010. The relevant regulation text is found at § 414.902 and § 414.904. At the time that the CY 2011 PFS final rule with comment period was published, it was not apparent how or when the new FDA abbreviated approval pathway would be implemented or when biosimilar products would be approved for marketing in the United States. The FDA approved the first biosimilar product under the new biosimilar approval pathway required by the Affordable Care Act on March 6, 2015.

Since 2010, we have continued to follow the implementation of the FDA biosimilar approval process and the emerging biosimilar marketplace. As biosimilars are now beginning to enter the marketplace, we have also reviewed the existing guidance on Medicare payment for these products. Our review has revealed a potential inconsistency between our interpretation of the statutory language at section 1847A(b)(8) of the Act and regulation text at § 414.904(j). To make the regulation text more consistent with our interpretation of the statutory language, we are proposing to amend the regulation text at § 414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code. We are also proposing to amend the regulation text at § 414.914(j) to update the effective date of this provision from July 1, 2010 to January 1, 2016, the anticipated effective date of the CY 2016 Physician Fee Schedule Final Rule with Comment Period. We welcome comments about these proposals.

We would also like to take this opportunity to discuss and clarify some other details of Part B biosimilar payment policy. First, we plan to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. In general, this means that products that rely on a common reference product's biologics license application will be grouped into the same payment calculation. This approach, which is similar to the ASP calculation for multiple source drugs, is authorized by section 1847A(b)(8)(A) of the Act, which states that the payment determination for a biosimilar biological product is determined using the methodology in paragraph 1847A(b)(6) applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph.

Second, we would like to describe how payment for newly approved biosimilars will be determined. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73393 and 73394), we anticipate that as subsequent biosimilar biological products are approved, we will receive manufacturers' ASP sales data through the ASP data submission process and publish national payment amounts in a manner that is consistent with our current approach to other drugs and

biologicals that are paid under section 1847A of the Act and set forth in 42 CFR part 414 subpart J. Until we have collected sufficient sales data as reported by manufacturers, payment limits will be determined in accordance with the provisions in section 1847A(c)(4) of the Act. If no manufacturer data is collected, prices will be determined by local contractors using any available pricing information, including provider invoices. As with newly approved drugs and biologicals (including biosimilars), Medicare part B payment would be available once the product is approved by the FDA. Payment for biosimilars (and other drugs and biologicals that are paid under part B) may be made before a HCPCS code has been released, provided that the claim is reasonable and necessary, and meets applicable coverage and claims submission criteria.

We would also like to clarify how wholesale acquisition cost (WAC) data may be used by CMS for Medicare payment of biosimilars in accordance with the provisions in section 1847A(c)(4) of the Act. Section 1847A(c)(4) of the Act authorizes the use of a WAC-based payment amount in cases where the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount. Once the wholesale acquisition cost (WAC) data is available from the pharmaceutical pricing compendia and when WAC-based payment amounts are utilized by CMS to determine the national payment limit for a biosimilar product, the payment limit will be 106 percent of the WAC of the biosimilar product; the reference biological product will not be factored into the WAC-based payment limit determination. This approach is consistent with partial quarter pricing that was discussed in rulemaking in the CY 2011 PFS final rule with comment period (75 FR 73465 and 73466) and with statutory language at section 1847A(c)(4) of the Act. Once ASP information is available for a biosimilar product, and when partial quarter pricing requirements no longer apply, the Medicare payment limit for a biosimilar product will be determined based on ASP data.

F. Productivity Adjustment for the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity. The year that the productivity adjustment is effective varies by payment system. Specifically, section 3401 of the Affordable Care Act requires that in CY 2011 (and in subsequent years) update factors under the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the DMEPOS fee schedule be adjusted by changes in economy-wide productivity. Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to add clause (xi)(II), which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics (BLS) Web site at *http://www.bls.gov/mfp.*

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projection of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which we contract to forecast the components of MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2011 and CY 2012 PFS final rules with comment period (75 FR 73394 through 73396, 76 FR 73300 through 73301), we set forth the current methodology to generate a forecast of MFP. We identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series. Beginning with CY 2016, for the AFS, CLFS and DMEPOS fee schedule, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with CY 2016. A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

G. 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) directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. This proposed rule outlines the initial component of the new Medicare AUC program and our plan for implementing the remaining components.

1. Background

In general, AUC are a set of individual criteria that 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). 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 context.

We believe the goal of this statutory AUC program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging. Professional medical societies, health systems, and academic institutions have been designing and implementing AUC for decades. Experience and published studies alike show that results are best when AUC are built on an evidence base that considers patient health outcomes, weighing the benefits and harms of alternative care options, and integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams collectively identify key clinical processes and then develop bottom-up, evidence-based AUC or guidelines that are embedded into clinical workflows, and become the organizing principle of care delivery (Aspen 2013). Feedback loops, an essential component, compare provider performance and patient health outcomes to individual, regional and national benchmarks.

There is also consensus that AUC programs built on evidence-based medicine and applied in a QI context are the best method to identify appropriate care and eliminate inappropriate care, and are preferable to across-the-board payment reductions that do not differentiate interventions that add value from those that cause harm or add no value.

2. Previous AUC Experience

The first CMS experience with AUC, the Medicare Imaging Demonstration (MID), was required by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Designed as an alternative to prior authorization, the MID's purpose was to examine whether provider exposure to appropriateness guidelines would reduce inappropriate utilization of advanced imaging services. In the 2-year demonstration which began in October 2011, nearly 4,000 physicians, grouped into one of five conveners across geographically and organizationally diverse practice settings, ordered a total of nearly 50,000 imaging studies.[1]

In addition to the outcomes of the MID (*http://www.rand.org/content/dam/rand/pubs/research_reports/RR700/RR706/RAND_RR706.pdf*), we considered others' experiences and results from implementation of imaging AUC and other evidence-based clinical guidelines at healthcare organizations such as Brigham & Women's, Intermountain Healthcare, Kaiser, Massachusetts General Hospital, and Mayo, and in states such as Minnesota. From these experiences, and analyses of them by medical societies and others, general agreement on at least two key points has emerged. First, AUC, and the clinical decision support (CDS) mechanisms through which providers access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the provider in the overall patient workup, treatment and follow-up. Imaging would appear as key nodes within the clinical management decision tree. The end goal of using AUC is to improve patient health outcomes. In reality, however, many providers may encounter AUC through a CDS mechanism for the first time at the point of image ordering. The CDS would ideally bring the provider back to that specific clinical condition and work-up scenario to ensure and simultaneously document the appropriateness of the imaging test.

However, there are different views about how best to roll out AUC into clinical practice. One opinion is that it is best to start with as comprehensive a library of individual AUC as possible to avoid the frustration, experienced and voiced by many practitioners participating in the MID, of spending time navigating the CDS tool only to find that, about 40 percent of the time, no AUC for their patient's specific clinical condition existed. The other opinion is that, based on decades of experience rolling out AUC in the context of robust QI programs, it is best to focus on a few priority clinical areas (for example, low back pain) at a time, to ensure that providers fully understand the AUC they are using, including when they do not apply to a particular patient. This same group also believes, based on experience with the MID, that too many low-evidence alerts or rules simply create ''alert fatigue.'' They envision that, rather than navigating through a CDS to find relevant AUC, providers would simply enter the patient's condition and a message would pop up stating whether AUC existed for that condition.

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 from day one a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee competing sets of AUC developed by different provider-led entities, and competing CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directs us to establish a new program to promote the use of AUC. In section 1834(q)(1)(B) of the Act, AUC are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual.

4. 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) 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)). In this proposed rule, we primarily address the first component under section 1834(q)(2)—the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1).

Section 1834(q)(1) of the Act describes the program and provides definitions of terms. The program is required to promote the use of AUC for applicable imaging services furnished in an applicable setting by ordering professionals and furnishing professionals. Section 1834(q)(1) of the Act provides definitions for AUC, applicable imaging service, applicable setting, ordering professional, and furnishing professional. An ''applicable imaging service'' under section 1834(q)(1)(C) of the Act must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines ''advanced diagnostic imaging services'' to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services we may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services.

Section 1834(q)(2)(A) of the Act requires the Secretary to specify applicable AUC for applicable imaging services, through rulemaking and in consultation with physicians, practitioners and other stakeholders, by November 15, 2015. Applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities. Section 1834(q)(2)(B) of the Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based,

[1] Timbie J, Hussey P, Burgette L, et al. Medicare Imaging Demonstration Final Evaluation: Report to Congress. 2014 The Rand Corporation

and are based on studies that are published and reviewable by stakeholders. Section 1834(q)(2)(C) of the Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them, and to make any needed updates or revisions through rulemaking. Section 1834(q)(2)(D) of the Act specifies that, if the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service.

The PAMA was enacted into law on April 1, 2014. Implementation of many aspects of the amendments made by section 218(b) requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted. The PFS proposed rule is published in late June or early July each year. For the new Medicare AUC program to have been a part of last year's proposed rule (CY 2015), we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. Additionally, given the complexity of the program to promote the use of AUC for advanced imaging services established under section 1834(q) of the Act, we believed it was imperative to consult with physicians, practitioners and other stakeholders in advance of developing proposals to implement the program. In the time since the legislation was enacted, we have met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program. Having this open door with stakeholders has greatly informed our proposed policy. In addition, before AUC can be specified as directed by section 1834(q)(2)(A) of the Act, there is first the need to define what AUC are and to specify the process for developing them. To ensure transparency and meet the requirements of the statute, we are proposing to implement section 1834(q)(2) of the Act by first establishing through rulemaking a process for specifying applicable AUC and proposing the requirements for AUC development. Under our proposal, the specification of AUC under section 1834(q)(2)(A) of the Act will flow from this process.

We are also proposing to define the term, ''provider-led entity,'' which is included in section 1834(q)(1)(B) of the Act so that the public has an opportunity to comment, and entities meeting the definition are aware of the process by which they may become qualified under Medicare to develop or endorse AUC. Under our proposed process, once a provider-led entity is qualified (which includes rigorous AUC development requirements involving evidence evaluation, as provided in section 1834(q)(2)(B) of the Act and proposed in this proposed rule) the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act.

The second major component of the Medicare AUC program is the identification of qualified CDS mechanisms that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. We envision a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user. The ordering professional would input information regarding the clinical presentation of the patient into the CDS tool, which may be a feature of or accessible through an existing system, and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems. This would minimize burden on provider teams and avoid duplicate documentation.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDS mechanisms 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 CDS mechanisms that are independent of certified EHR technology; and a CDS mechanism established by the Secretary.

However, all CDS mechanisms 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 supporting documentation for the applicable imaging service that is ordered; where there is more than one applicable AUC 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 CDS 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 CDS mechanisms.

We are not including proposals to implement section 1834(q)(3) of the Act in this proposed rule. We need to first establish, through notice and comment rulemaking, the process for specifying applicable AUC. Specified applicable AUC would serve as the inputs to any qualified CDS mechanism, therefore, these must first be identified so that prospective tool developers are able to establish relationships with AUC developers. In addition, we anticipate that in PFS rulemaking for CY 2017, we will provide clarifications, develop definitions and establish the process by which we will specify qualified CDS mechanisms. The requirements for qualified CDS mechanisms set forth in section 1834(q)(3)(B) of the Act will also be vetted through PFS rulemaking for CY 2017 so that mechanism developers have a clear understanding and notice regarding the requirements for their tools. The CY 2017 proposed rule would be published at the end of June or in early July of 2016, be open for a period of public comment, and then the final rule would be published by November 1, 2016. We anticipate that the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 PFS final rule. In advance of these actions, we will continue to work with stakeholders to understand how to ensure that appropriate mechanisms are available, particularly with respect to standards for certified health IT, including EHRs, that can enable interoperability of AUC across systems.

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 listed qualified CDS mechanism 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 CDS mechanism. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders the imaging service is usually not the same professional who bills Medicare for the test 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 a hardship exemption. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the physician fee schedule, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We are not including proposals to implement section 1834(q)(4) of the Act in this proposed rule. Again, it is important that we first establish through notice and comment rulemaking the process by which applicable AUC will be specified as well as the CDS mechanisms through which ordering providers would access them. We anticipate including further discussion and adopting policies regarding claims-based reporting requirements in the CY 2017 and CY 2018 rulemaking cycles.

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 including proposals to implement these sections in this proposed rule, we are proposing to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking. In this rule, we propose a process to provide clarity around priority clinical areas.

The concept of priority clinical areas allows CMS to implement an AUC program that combines two approaches to implementation. Under our proposed policy, while potentially large volumes of AUC would become specified across clinical conditions and advanced imaging technologies, we believe this rapid roll out of specified AUC should be balanced with a more focused approach to 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.

In future rulemaking, with the benefit of public comments, we will establish priority clinical areas and expand them over time. Also in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals.

5. Proposals for Implementation

We are proposing to amend our regulations to add a new § 414.94, ''Appropriate Use Criteria for Certain Imaging Services.''

a. Definitions

In § 414.94 (b), we are proposing to codify and add language to clarify some of the definitions provided in section 1834(q)(1) 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 of the proposed rule, we provide a description of the terms we are proposing to codify to facilitate understanding and encourage public comment on the proposed AUC program.

Due to circumstances unique to imaging, it is important to note that there is an ordering professional (the physician or practitioner that orders that the imaging service be performed) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the radiologic interpretation of the image) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This proposed AUC program only applies in applicable settings. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. The inpatient hospital setting, for example, is not an applicable setting. Further, the proposed program only applies to applicable imaging services. These are advanced diagnostic imaging services for which one or more applicable AUC apply, one or more qualified CDS mechanisms is available, and one of those mechanisms is available free of charge.

We are proposing to clarify the definition for appropriate use criteria, which is defined in statute to include only criteria developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based. To further describe AUC, we are proposing to add the following language to this definition: AUC are a collection of individual appropriate use criteria. Individual criteria are information presented 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 the purposes of implementing this program, we are proposing to define new terms in § 414.94(b). A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians) or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems). Applicable AUC become specified when they are developed, modified or endorsed by a qualified provider-led entity. A provider-led entity is not considered qualified until CMS makes a determination via the qualification process discussed in this proposal. We are introducing priority clinical areas to inform ordering professionals and furnishing professionals of the clinical topics, clinical topics and imaging modalities or imaging modalities that may be identified by the agency through annual rulemaking and in consultation with stakeholders which may be used in the identification of outlier ordering professionals.

The proposed definitions in § 414.94 are important in understanding our proposals for implementation. Only AUC developed, modified or endorsed by organizations meeting the definition of provider-led entity would be considered specified applicable AUC. As required by the statute, specified applicable AUC, which encompass all AUC developed, modified or endorsed by qualified provider-led entities, must be consulted and such consultation must be reported on the claim for applicable imaging services. To assist in identification of outlier ordering professionals, we propose to focus on priority clinical areas. Priority clinical areas would be associated with a subset of specified AUC.

b. AUC Development by Provider-Led Entities

In § 414.94, we are proposing to include regulations to implement the first component of the Medicare AUC program—specification of applicable AUC. We are first proposing a process by which provider-led entities (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for provider-led entities to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we propose to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for the AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. It is not feasible for us to review every individual criterion. Rather, we propose to establish a qualification process and requirements for qualified provider-led entities in order to ensure that the AUC development or endorsement processes used by a provider-led entity result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B). Therefore, we propose that AUC developed, modified, or endorsed by qualified provider-led entities will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

In order to become and remain a qualified provider-led entity, we propose to require a provider-led entity to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. The first proposed requirement is related to the evidentiary review process for individual criteria. Entities must engage in a systematic literature review of the clinical topic and relevant imaging studies. We would expect the literature review to include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the provider-led entity must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. Consideration of relevant published evidence-based guidelines and consensus statements by professional medical specialty societies must be part of the evidence assessment. Published consensus statements may form part of the evidence base of AUC and would be subject to the evidentiary grading methodology as any other evidence identified as part of a systematic review.

In addition, we propose that the provider-led entity's AUC development process must be led by at least one multidisciplinary team with autonomous governance that is accountable for developing, modifying, or endorsing AUC. At a minimum, the team must be composed of three members including one with expertise in the clinical topic related to the criterion and one with expertise in imaging studies related to the criterion. We encourage such teams to be larger, and include experts in each of the following domains: Statistical analysis (such as biostatics, epidemiology, and applied mathematics); clinical trial design; medical informatics; and quality improvement. A given team member may be the team's expert in more than one domain. These experts should contribute substantial work to the development of the criterion, not simply review the team's work.

Another important area to address that provides additional assurance regarding quality and evidence-based AUC development is the disclosure of conflicts of interest. We believe it is appropriate to impose relatively stringent requirements for public transparency and disclosure of potential conflicts of interest for anyone participating with a provider-led entity in the development of AUC. We propose that the provider-led entity must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The provider-led entity must disclose any direct or indirect relationships, as well as ownership or investment interests, among the multidisciplinary team members or immediate family members and organizations that may financially benefit from the AUC that are being considered for development, modification or endorsement.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we propose that the provider-led entity must maintain on its Web site each criterion that is part of the AUC that the entity has considered or is considering for development, modification, or endorsement. This public transparency of individual criteria is critical not only to ordering and furnishing professionals, but also to patients and other health care providers who may wish to view all available AUC.

Although evidence should be the foundation for the development, modification and endorsement of AUC, we recognize that not all aspects of a criterion will be evidence-based, and that a criterion does not exist for every clinical scenario. We believe it is important for AUC users to understand which aspects of a criterion are evidence-based and which are consensus-based. Therefore, we propose that key decision points in individual criteria be graded in terms of strength of evidence using a formal, published, and widely recognized methodology. This level of detail must be part of each AUC posted to the entity's Web site.

It is critical that as provider-led entities develop large collections of AUC, they have a transparent process for the timely and continual review of each criterion, as there are sometimes rapid changes in the evidence base for certain clinical conditions and imaging studies.

Finally, we propose that a provider-led entity's process for developing, modifying, or endorsing AUC (which would be inclusive of the requirements being proposed in this rule) must be publicly posted on the entity's Web site.

We believe it is important to fit AUC to local circumstances and populations, while also ensuring a rigorous due process for doing so. Under our proposed AUC program, local adaptation of AUC might happen in three ways. First, compatibility with local practice is something that ordering professionals can assess when selecting AUC for consultation. Second, professional medical societies (many of which have state chapters) and large health systems (which incorporate diverse practice settings, both urban and rural) that become qualified provider-led entities can get local feedback at the outset and build alternative options into the design of their AUC. Third, local provider-led entities can themselves become qualified to develop, modify, or endorse AUC.

c. Process for Provider-Led Entities To Become Qualified To Develop, Endorse or Modify AUC

We are proposing that provider-led entities must apply to CMS to become qualified. We are proposing that entities that believe they meet the definition of provider-led submit applications to us that document adherence to each of the qualification requirements. The application must include a statement as to how the entity meets the definition of a provider-led entity. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be

qualified provider-led entities will be posted to our Web site by the following June 30 at which time all AUC developed or endorsed by that provider-led entity will be considered to be specified AUC. All qualified provider-led entities must re-apply every 6 years and their applications must be received by January 1 during the 5th year of their approval. Note that the application is not a CMS form; rather it is created by the applicant entity.

d. Identifying Priority Clinical Areas

Section 1834(q)(4) of the Act requires that, beginning January 1, 2017, ordering professionals must consult applicable AUC using a qualified CDS mechanism when ordering applicable imaging services for which payment is made under applicable payment systems, and that furnishing professionals must report the results of this consultation on Medicare claims. Section 1834(q)(5) of the Act further provides for the identification of outlier ordering professionals based on a low adherence to applicable AUC. We are proposing to identify priority clinical areas of AUC that we will use in identifying outlier ordering professionals. Although there is no consequence to being identified as an outlier ordering professional until January 2020, it is important to allow ordering and furnishing professionals as much time as possible to use and familiarize themselves with the specified applicable AUC that will eventually become the basis for identifying outlier ordering professionals.

To identify these priority clinical areas, we may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. We may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. We are proposing to annually solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in CY 2017. To further assist us in developing the list of proposed priority clinical areas, we are proposing to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), a CMS FACA compliant committee, as needed to examine the evidence surrounding certain clinical areas.

Specified applicable AUC falling within priority clinical areas may factor into the low-adherence calculation when identifying outlier ordering professionals for the prior authorization component of this statute, which is slated to begin in 2020. Future rulemaking will address further details.

e. Identification of Non-Evidence Based AUC

Despite our proposed provider-led entity qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence based criteria may be developed or endorsed by qualified provider-led entities. Therefore, we are proposing a process by which we would identify and review potentially non-evidence-based criteria that fall within one of our identified priority clinical areas. We are proposing to accept public comment through annual PFS rulemaking so that the public can assist in identifying AUC that potentially are not evidence-based. We foresee this being a standing request for comments in all future rules regarding AUC. We are proposing to use the MEDCAC to further review the evidentiary basis of these identified AUC, as needed. The MEDCAC has extensive experience in reviewing, interpreting, and translating evidence. If through this process, a number of criteria from an AUC library are identified as being insufficiently evidence-based, and the provider-led entity that produced the library does not make a good faith attempt to correct these in a timely fashion, this information could be considered when the provider-led entity applies for re-qualification.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a new Medicare AUC program for advanced imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic 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 vast.

We 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 CDS mechanism developers. It is for these reasons we are proposing a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

In summary, we are proposing definitions of terms necessary to implement the AUC program. We are particularly seeking comment on the proposed definition of provider-led entity as these are the organizations that have the opportunity to become qualified to develop, modify or endorse specified AUC. We are also proposing an AUC development process which allows some flexibility for provider-led entities but sets standards including an evidence-based development process and transparency. In addition, we are proposing the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we are proposing to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invite the public to submit comments on these proposals.

H. Physician Compare Web Site

1. Background and Statutory Authority

As required by section 10331(a)(1) of the Affordable Care Act, by January 1, 2011, we developed a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals (EPs) who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act. We launched the first phase of Physician Compare on December 30, 2010 (*http://www.medicare.gov/physiciancompare*). In the initial phase, we posted the names of EPs that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

We also implemented, consistent with section 10331(a)(2) of the Affordable Care Act, a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures for reporting periods beginning no earlier than January 1, 2012. We met this requirement in advance of the statutory deadline of January 1, 2013, as outlined below, and plan to continue addressing elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System (PQRS).

- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

In developing and implementing the plan, section 10331(b) requires that we include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and EPs whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. We have established a 30-day preview period for all measurement performance data that will allow physicians and other EPs to view their data as it will appear on the Web site in advance of publication on Physician Compare (77 FR 69166, 78 FR 74450, and 79 FR 67770). Details of the preview process will be communicated directly to those with measures to preview and will also be published on the Physician Compare Initiative page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/*) in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, when selecting quality measures for Physician Compare. We also continue to get general input from stakeholders on Physician Compare through a variety of means, including rulemaking and different forms of stakeholder outreach (for example, Town Hall meetings, Open Door Forums, webinars, education and outreach, Technical Expert Panels, etc.).

We submitted a report to the Congress in advance of the January 1, 2015 deadline, as required by section 10331(f) of the Affordable Care Act, on Physician Compare development, including information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we plan to continue to publicly report physician performance information on Physician Compare.

2. Public Reporting of Performance and Other Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare, including a full redesign in 2013. Currently, Web site users can view information about approved Medicare professionals such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, residency, and American Board of Medical Specialties (ABMS) board certification information. In addition, for group practices, users can view group practice names, specialties, practice locations, Medicare assignment status, and affiliated professionals.

In addition, there is a section on each Medicare professional's profile page indicating with a green check mark the quality programs under which the EP satisfactorily or successfully reported. The Web site will continue to post annually the names of individual EPs who satisfactorily report under PQRS, EPs who successfully participate in the Medicare Electronic Health Record (EHR) Incentive Program as authorized by section 1848(o)(3)(D) of the Act, and EPs who report PQRS measures in support of Million Hearts (79 FR 67763). A proposed change to the Million Hearts indicator for 2016 data is discussed below.

With the 2013 redesign of the Physician Compare Web site, we added a quality programs section to each group practice profile page, as well. We will continue to indicate which group practices are satisfactorily reporting in the Group Practice Reporting Option (GPRO) under PQRS (79 FR 67763). The Physician Compare Web site also contains a link to the Physician Compare downloadable database (*https://data.medicare.gov/data/physician-compare*), including information on this quality program participation.

We continue to implement our plan for a phased approach to public reporting performance information on the Physician Compare Web site. Under the first phase of this plan, we established that GPRO measures collected under PQRS through the Web Interface for 2012 would be publicly reported on Physician Compare (76 FR 73419 through 73420). We further expanded the plan by including on the Physician Compare Web site the 2013 group practice-level PQRS measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) reported via the Web Interface, and planned to report composite measures for DM and CAD in 2014, as well (77 FR 69166).

The 2012 GPRO measures were publicly reported on Physician Compare in February 2014. The 2013 PQRS GPRO DM and GPRO CAD measures collected via the Web Interface that met the minimum sample size of 20 patients and proved to be statistically valid and reliable were publicly reported on Physician Compare in December 2014. The composite measures were not reported, however, as some items included in the composites were no longer clinically relevant. If the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the performance rate on that measure is not publicly reported. On the Physician Compare Web site, we only publish those measures that are statistically valid and reliable, and therefore, most likely to help consumers make informed decisions about the Medicare professionals they choose to meet their health care needs. In addition, we do not publicly report first year measures, meaning new PQRS and non-PQRS measures that have been available for

reporting for less than one year, regardless of reporting mechanism. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for public reporting.

Measures must be based on reliable and valid data elements to be useful to consumers. Therefore, for all proposed measures available for public reporting, including both group and individual EP level measures—regardless of reporting mechanism, only those proposed measures that prove to be valid, reliable, and accurate upon analysis and review at the conclusion of data collection and that meet the established public reporting criteria of a minimum sample size of 20 patients will be included on Physician Compare. For information on how we determine the validity and reliability of data and other statistical analyses we perform, refer to the CY 2015 PFS final rule with comment period (79 FR 67764 through 79 FR 67765).

We will also continue to include an indicator of which reporting mechanism was used and to only include on the site measures deemed statistically comparable.[2] We will continue to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, not all of these measures would necessarily be included on the Physician Compare profile pages. Consumer testing has shown profile pages with too much information and measures that are not well understood by consumers can negatively impact a consumer's ability to make informed decisions. Our analysis of the collected measure data, along with consumer testing and stakeholder feedback, will determine specifically which measures are published on Web site profile pages. Statistical analyses, like those specified above, will ensure the measures included are statistically valid and reliable and comparable across data collection mechanisms. Stakeholder feedback will help us to ensure that all publicly reported measures meet current clinical standards. When measures are finalized in advance of the time period in which they are collected, it is possible that clinical guidelines can change rendering a measure no longer relevant. Publishing that measure can lead to consumer confusion regarding what best practices their health care professional should be subscribing to. We will continue to reach out to stakeholders in the professional community, such as specialty societies, to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.

The primary goal of Physician Compare is to help consumers make informed health care decisions. If a consumer does not properly interpret a quality measure and thus misunderstands what the quality score represents, the consumer cannot use this information to make an informed decision. Through concept testing, we will test with consumers how well they understand measures presented using plain language. Such consumer testing will help us gauge how measures are understood and the kinds of measures that are most relevant to consumers. This will be done to help ensure that the information included on Physician Compare is as consumer friendly and consumer focused as possible.

As is the case for all measures published on Physician Compare, individual EPs and group practices will be given a 30-day preview period to view their measures as they will appear on Physician Compare prior to the measures being published. As in previous years, we will fully explain the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period.

We also report certain Accountable Care Organization (ACO) quality measures on Physician Compare (76 FR 67802, 67948). Because EPs that bill under the TIN of an ACO participant are considered to be a group practice for purposes of qualifying for a PQRS incentive under the Medicare Shared Savings Program (Shared Savings Program), we publicly report ACO performance on quality measures on the Physician Compare Web site in the same way as we report performance on quality measures for group practices participating under PQRS. Public reporting of performance on these measures is presented at the ACO level only. The first subset of ACO measures was also published on the Web site in February 2014. ACO measures can be viewed by following the ''Accountable Care Organization (ACO) Quality Data'' link on the homepage of the Physician Compare Web site (*http://medicare.gov/physiciancompare/aco/search.html*).

ACOs will be able to preview their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare. The quality reports will indicate the measures that are available for public reporting. ACO measures will be publicly reported in plain language, so a crosswalk linking the technical language included in the Quality Report and the plain language that will be publicly reported will be provided to ACOs at least 30 days prior to the start of public reporting.

As part of our public reporting plan for Physician Compare, we also have available for public reporting patient experience measures, specifically reporting the CAHPS for PQRS measures, which relate to the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) data, for group practices of 100 or more EPs reporting data in 2013 under PQRS and for ACOs participating in the Shared Savings Program (77 FR 69166 and 69167). The 2013 CAHPS data for ACOs were publicly reported on Physician Compare in December 2014.

We continued to expand our plan for publicly reporting data on Physician Compare in 2015. We plan to make all group practice-level measures collected through the Web Interface for groups of 25 or more EPs participating in 2014 under the PQRS and for ACOs participating in the Shared Savings Program available for public reporting in CY 2015 (78 FR 74449). We also plan to publicly report performance on certain measures that group practices report via registries and EHRs for the 2014 PQRS GPRO (78 FR 74451). Specifically, we finalized a decision to make available for public reporting on Physician Compare performance on 16 registry measures and 13 EHR measures in CY 2015 (78 FR 74451). These measures are consistent with the measures available for public reporting via the Web Interface.

In CY 2015, CAHPS measures for group practices of 100 or more EPs who participate in PQRS, regardless of data submission method, and for Shared Savings Program ACOs reporting through the Web Interface or other CMS-approved tool or interface are available for public reporting (78 FR 74452). In addition, twelve 2014 summary survey measures for groups of 25 to 99 EPs collected via any certified CAHPS vendor regardless of PQRS participation are available for public reporting (78 FR 74452). For ACOs participating in the Shared Savings Program, the patient experience measures that are included in the Patient/Caregiver Experience domain of the Quality Performance Standard under the Shared Savings Program will be available for public reporting in CY 2015 (78 FR 74452).

[2] By statistically comparable, CMS means that the quality measures are analyzed and proven to measure the same phenomena in the same way regardless of the mechanism through which they were collected.

In late CY 2015, certain 2014 individual PQRS measure data reported by individual EPs are also available for public reporting. Specifically, we will make available for public reporting 20 individual measures collected through a registry, EHR, or claims (78 FR 74453 through 74454). These are measures that are in line with those measures reported by groups via the Web Interface.

Finally, in support of the HHS-wide Million Hearts initiative, performance rates on measures in the PQRS Cardiovascular Prevention measures group at the individual EP level for data collected in 2014 for the PQRS are available for public reporting in CY 2015 (78 FR 74454).

We continue to expand public reporting on Physician Compare by making an even broader set of quality measures available for publication on the Web site in CY 2016. All 2015 group-level PQRS measures across all group reporting mechanisms—Web Interface, registry, and EHR—are available for public reporting on Physician Compare in CY 2016 for groups of 2 or more EPs (79 FR 67769). Similarly, we decided that all measures reported by ACOs participating in the Shared Savings Program will be available for public reporting on Physician Compare.

Understanding the value of patient experience data for Physician Compare, CMS decided to report twelve 2015 CAHPS for PQRS summary survey measures for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor, are available for public reporting in CY 2016 (79 FR 67772).

To provide the opportunity for more EPs to have measures included on Physician Compare, and to provide more information to consumers to make informed decisions about their health care, we will make available for public reporting in CY 2016 on Physician Compare all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims (79 FR 67773).

Furthermore, in support of the HHS-wide Million Hearts initiative, we will publicly report the performance rates on the four, 2015 PQRS measures reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.

To further support the expansion of quality measure data available for public reporting on Physician Compare and to provide more quality data to consumers to help them make informed decisions, CMS finalized 2015 Qualified Clinical Data Registry (QCDR) PQRS and non-PQRS measure data collected at the individual EP level are available for public reporting. The QCDR is required to declare during their self-nomination if they plan to post data on their own Web site and allow Physician Compare to link to it or if they will provide data to CMS for public reporting on Physician Compare. Measures collected via QCDRs must also meet the established public reporting criteria. Both PQRS and non-PQRS measures that are in their first year of reporting by a QCDR will not be available for public reporting (79 FR 67774 through 67775).

See Table 18 for a summary of our previously finalized policies for public reporting data on Physician Compare.

TABLE 18—SUMMARY OF PREVIOUSLY FINALIZED POLICIES FOR PUBLIC REPORTING ON PHYSICIAN COMPARE

Data collection year	Public reporting year	Reporting mechanism(s)	Quality measures and data for public reporting
2012	2013	Web Interface (WI), EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx Incentive Program, and participants in the EHR Incentive Program.
2012	February 2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices reporting under PQRS with a minimum sample size of 25 patients and Shared Savings Program ACOs.
2013	2014	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx Incentive Program, and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2013	December 2014	WI	3 DM and 1 CAD measures collected via the WI for groups of 25 or more EPs with a minimum sample size of 20 patients.
2013	December 2014	Survey Vendor	6 CAHPS for ACO summary survey measures for Shared Savings Program ACOs.
2014	Expected to be 2015	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry	All measures reported via the WI, 13 EHR, and 16 registry measures for group practices of 2 or more EPs reporting under PQRS with a minimum sample size of 20 patients. Include composites for DM and CAD, if available.
2014	Expected to be late 2015	WI, Survey Vendor Administrative Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACO and claims based measures.
2014	Expected to be late 2015	WI, Certified Survey Vendor.	Up to 12 CAHPS for PQRS summary measures for groups of 100 or more EPs reporting via the WI and group practices of 25 to 99 EPs reporting via a CMS-approved certified survey vendor.
2014	Expected to be late 2015	Registry, EHR, or Claims	A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through registry, EHR, or claims with a minimum sample size of 20 patients.
2014	Expected to be late 2015	Registry	Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.

TABLE 18—SUMMARY OF PREVIOUSLY FINALIZED POLICIES FOR PUBLIC REPORTING ON PHYSICIAN COMPARE—Continued

Data collection year	Public reporting year	Reporting mechanism(s)	Quality measures and data for public reporting
2015	Expected to be late 2016	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who report 4 individual PQRS measures in support of Million Hearts.
2015	Expected to be late 2016	WI, EHR, Registry	All PQRS measures for group practices of 2 or more EPs.
2015	Expected to be late 2016	WI, Survey Vendor Administrative Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs and claims based measures.
2015	Expected to be late 2016	Certified Survey Vendor	All CAHPS for PQRS measures reported for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2015	Expected to be late 2016	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims.
2015	Expected to be late 2016	Registry, EHR, or Claims	4 PQRS measures reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.
2015	Expected to be late 2016	QCDR	All individual EP QCDR measures, including PQRS and non-PQRS measures.

3. Proposed Policies for Public Data Disclosure on Physician Compare

We are expanding public reporting on Physician Compare by continuing to make a broad set of quality measures available for publication on the Web site. We started the phased approach with a small number of possible PQRS GPRO Web Interface measures for 2012 and have been steadily building on this to provide Medicare consumers with more information to help them make informed health care decisions. As a result, we are now proposing to add new data elements to the individual EP and/or group practice profile pages and to continue to publicly report a broad set of quality measures on the Web site.

a. Value Modifier

We propose to expand the section on each individual EP and group practice profile page that indicates Medicare quality program participation with a green check mark to include the names of those individual EPs and group practices who received an upward adjustment for the Value Modifier (VM). We propose to include this on Physician Compare annually. For the 2018 VM, this information would be based on 2016 data and included on the site no earlier than late 2017. The VM upward adjustment indicates that a physician or group has achieved one of the following: higher quality care at a lower cost; higher quality care at an average cost; or average quality care at a lower cost. The first goal of the HHS Strategic Plan is to strengthen health care. One of the ways to do this is to reduce the growth of health care costs while promoting high-value, effective care (Objective D, Strategic Goal 1).[3] This VM indicator can help consumers identify higher quality care provided at a lower cost. This means this type of quality information may be very useful to consumers as they work to choose the best possible health care available to them. Including the check mark is a way to share what can be a very complex concept in a user-friend, easy-to-understand format. We believe this is a positive first step in making this important information available to the public in a way that is most likely to be accurately interpreted and beneficial. We solicit comments on this proposal.

b. Million Hearts

In support of the HHS-wide Million Hearts initiative, we include an indicator for individual EPs who choose to report on specific ''ABCS'' (Appropriate Aspirin Therapy for those who need it, Blood Pressure Control, Cholesterol Management, and Smoking Cessation) measures (79 FR 67764). Based on available measures the criteria for this indicator have evolved over time. In 2015, an indicator was included if EPs satisfactorily reported four individual PQRS Cardiovascular Prevention measures. In previous years, the indicator was based on satisfactory reporting of the Cardiovascular Prevention measures group, which was not available via PQRS for 2015. To further support this initiative, we now propose to include on Physician Compare annually in the year following the year of reporting (for example, 2016 data will be included on Physician Compare in 2017) an indicator for individual EPs who satisfactorily report the new Cardiovascular Prevention measures group being proposed under PQRS, should this measures group be finalized. The Million Hearts initiative's primary goal is to improve cardiovascular heart health, and therefore, we believe it is important to continue supporting the program and acknowledging those physicians and other health care professionals working to excel in performance on the ABCS. We solicit comments on this proposal.

c. PQRS GPRO and ACO Reporting

Understanding the importance of including quality data on Physician Compare to support the goals of section 10331(a) of the Affordable Care Act, we finalized in the CY 2015 PFS final rule with comment period (79 FR 67547) a decision to publicly report on Physician Compare all PQRS GPRO measures collected in 2015 via the Web Interface, registry, or EHR. We propose to continue to make available for public reporting on Physician Compare on an annual basis all PQRS GPRO measures across all PQRS group practice reporting mechanisms—Web Interface, registry, and EHR– for groups of 2 or more EPs available in the year following the year the measures are reported. Similarly, all measures reported by Shared Savings Program ACOs, including CAHPS for ACO measures, would be available for public reporting on Physician Compare annually in the year following the year the measures are reported. For group practice and ACO measures, the measure performance rate will be represented on the Web site. We solicit comments on this proposal.

d. Individual EP PQRS Reporting

Consumer testing indicates that consumers are looking for measures regarding individual doctors and other health care professionals. As a result, we plan to make available for public reporting on Physician Compare all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims (79 FR 67773). Through

[3] *http://www.hhs.gov/strategic-plan/goal1.html.*

stakeholder outreach and consumer testing we have learned that these PQRS quality data provide the public with useful information to help consumers make informed decisions about their health care. As a result, we propose to continue to make all PQRS measures across all individual EP reporting mechanisms available for public reporting on Physician Compare annually in the year following the year the measures are reported (for example, 2016 data will be included on Physician Compare in 2017). For individual EP measures, the measure performance rate will be represented on the Web site. We solicit comments on this proposal.

e. Individual EP and Group Practice QCDR Measure Reporting

Stakeholder outreach and consumer testing have repeatedly shown that consumers find individual EP quality measures valuable and helpful when making health care decisions. Consumers want to know more about the individual EPs they can make an appointment to see for their health care needs. And expanding group practice-level public reporting ensures that more quality data are available to assist consumers with their decision making. We do appreciate, however, that not all specialties have a full complement of available quality measures specific to the work they do currently available through PQRS. As a result, we decided to make individual EP level Qualified Clinical Data Registry (QCDR) measures–both PQRS and non-PQRS measures—available for public reporting starting with 2015 data (79 FR 67774 through 67775). To further support the availability of quality measure data most relevant for all specialties, we propose to continue to make available for public reporting on Physician Compare all individual EP level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year. In addition, we are now proposing to also make group practice level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year available for public reporting. Previously, the PQRS program only included QCDR data at the individual EP level. In this proposed rule, CMS is proposing, under the PQRS, to expand QCDR data to be available to group practices as well. In this case, group practice refers to a group of 2 or more EPs billing under the same Tax Identification Number (TIN). We propose to publicly report these data annually in the year following the year the measures are reported. For both EP and group level measures, the measure performance rate will be represented on the Web site. We solicit comments on these proposals.

The QCDR would be required to declare during its self-nomination if it plans to post data on its own Web site and allow Physician Compare to link to it or if the QDCR will provide data to us for public reporting on Physician Compare. After a QCDR declares a public reporting method, that decision is final for the reporting year. If a declaration is not made, the data would be considered available for public reporting on Physician Compare.

f. Benchmarking

We previously proposed (79 FR 40389) a benchmark that aligned with the Shared Savings Program ACO benchmark methodology finalized in the November 2011 Shared Savings Program final rule (76 FR 67898) and amended in the CY 2014 PFS final rule with comment period (78 FR 74759). Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark will allow consumers to more easily evaluate the information published by providing a point of comparison between groups and between individuals. However, given shortcomings when trying to apply the Shared Savings Program methodology to the group practice or individual EP setting, this proposal was not finalized. We noted we would discuss more thoroughly potential benchmarking methodologies with our stakeholders and evaluate other programs' methodologies to identify the best possible option for a benchmark for Physician Compare (79 FR 67772). To accomplish this, we reached out to stakeholders, including specialty societies, consumer advocacy groups, physicians and other health care professionals, measure experts, and quality measure specialists, as well as other CMS Quality Programs. Based on this outreach and the recommendation of our Technical Expert Panel (TEP), we propose to publicly report on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC™) [4] methodology annually based on the PQRS performance rates most recently available. For instance, in 2017 we would publicly report a benchmark derived from the 2016 PQRS performance rates. The specific measures the benchmark would be derived for would be determined once the data are available and analyzed. The benchmark would only be applied to those measures deemed valid and reliable and that are reported by enough EPs or group practices to produce a valid result (see 79 FR 67764 through 79 FR 67765 for a more detailed discussion regarding the types of analysis done to ensure data are suitable for public reporting). We solicit comments on this proposal.

ABC™ is a well-tested, data-driven methodology that allows us to account for all of the data collected for a quality measure, evaluate who the top performers are, and then use that to set a point of comparison for all of those groups or individual EPs who report the measure.

ABC™ starts with the pared-mean, which is the mean of the best performers on a given measure for at least 10 percent of the patient population—not the population of reporters. To find the pared-mean, we will rank order physicians or groups (as appropriate per the measure being evaluated) in order from highest to lowest performance score. We will then subset the list by taking the best performers moving down from best to worst until we have selected enough reporters to represent 10 percent of all patients in the denominator across all reporters for that measure.

We will derive the benchmark by calculating the total number of patients in the highest scoring subset receiving the intervention or the desired level of care, or achieving the desired outcome, and dividing this number by the total number of patients that were measured by the top performing doctors. This produces a benchmark that represents the best care provided to the top 10 percent of patients.

An Example: A doctor reports which of her patients with diabetes have maintained their blood pressure at a healthy level. There are four steps to establishing the benchmark for this measure.

(1) We look at the total number of patients with diabetes for all doctors who reported this diabetes measure.

(2) We rank doctors that reported this diabetes measure from highest performance score to lowest performance score to identify the set of top doctors who treated at least 10 percent of the total number of patients with diabetes.

(3) We count how many of the patients with diabetes who were treated by the top doctors also had blood pressure at a healthy level.

(4) This number is divided by the total number of patients with diabetes

[4] Kiefe CI, Weissman NW, Allison JJ, Farmer R, Weaver M, Williams OD. Identifying achievable benchmarks of care: concepts and methodology. International Journal of Quality Health Care. 1998 Oct; 10(5):443–7.

who were treated by the top doctors, producing the ABC™ benchmark.

To account for low denominators, ABC™ calls for the calculation of an adjusted performance fraction (AFP), a Bayesian Estimator. The AFP is calculated by dividing the actual number of patients receiving the intervention or the desired level of care plus 1 by the total number of patients in the total sample plus 2. This ensures that very small sample sizes do not over influence the benchmark and allows all data to be included in the benchmark calculation. To ensure that a sufficient number of cases are included by mean performance percent, ABC™ provides a minimum sufficient denominator (MSD) for each performance level. Together this ensures that all cases are appropriately accounted for and adequately figured in to the benchmark.

The ABC™ methodology for a publicly reported benchmark on Physician Compare would be based on the current year's data, so the benchmark would be appropriate regardless of the unique circumstances of data collection or the measures available in a given reporting year. We also propose to use the ABC™ methodology to generate a benchmark which can be used to systematically assign stars for the Physician Compare 5 star rating. ABC™ has been historically well received by the health care professionals and entities it is measuring because the benchmark represents quality while being both realistic and achievable; it encourages continuous quality improvement; and, it is shown to lead to improved quality of care.[5] [6] [7]

To summarize, we propose to publicly report on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology annually based on the PQRS performance rates most recently available (that is, in 2017 we would publicly report a benchmark derived from the 2016 PQRS performance rates), and use this benchmark to systematically assign stars for the Physician Compare 5 star rating. We solicit comments on this proposal.

g. Patient Experience of Care Measures

In the CY 2015 PFS final rule with comment period (79 FR 67547), we adopted a policy to publicly report patient experience data for all group practices of two or more EPs. Consumer testing shows that other patients' assessments of their experience resonate with consumers because it is important to them to hear about positive and negative experiences others have with physicians and other health care professionals. As a result, consumers report these patient experience data help them make an informed health care decision. Understanding the value consumers place on patient experience data and our commitment to reporting these data on Physician Compare, we propose to continue to make available for public reporting all patient experience data for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor, annually in the year following the year the measures are reported (for example, 2016 PQRS reported data will be included on the Web site in 2017). The patient experience data available that we propose to make available for public reporting are the CAHPS for PQRS measures, which include the CG–CAHPS core measures. For group practices, we propose to annually make available for public reporting a representation of the top box performance rate [8] for these 12 summary survey measures:

- Getting Timely Care, Appointments, and Information.
- How Well Providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.
- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping You to Take Medication as Directed.
- Stewardship of Patient Resources.

We solicit comments on this proposal.

h. Downloadable Database

(a) Addition of VM Information

To further aid in transparency, we also propose to add new data elements to the Physician Compare downloadable database (*https://data.medicare.gov/data/physician-compare*). Currently, the downloadable database includes all quality information publicly reported on Physician Compare, including quality program participation, and all measures submitted and reviewed and found to be statistically valid and reliable. We propose to add to the Physician Compare downloadable database for group practices and individual EPs the 2018 VM quality tiers for cost and quality, based on the 2016 data, noting if the group practice or EP is high, low, or average on cost and quality per the VM. We also propose to include a notation of the payment adjustment received based on the cost and quality tiers, and an indication if the individual EP or group practice was eligible to but did not report quality measures to CMS. The profile pages on Physician Compare are meant to provide information to average Medicare consumers that can help them identify quality health care and choose a quality clinician, while this database is geared toward health care professionals, industry insiders, and researchers who are more able to accurately use more complex data. Therefore, adding this information to the downloadable database promotes transparency and provides useful data to the public while we conduct consumer testing to ensure VM data beyond the indication for an upward adjustment discussed above can be packaged and explained in such a way that it is accurately interpreted, understood, and useful to average consumers. We solicit comments on this proposal.

(b) Addition of Utilization Data

In addition, we propose to add utilization data to the Physician Compare downloadable database. Utilization data is information generated from Medicare Part B claims on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals; and are currently available at (*http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html*). It provides counts of services and procedures rendered by health care professionals by Healthcare Common Procedure Coding System (HCPCS) code. Under section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. 114–10, § 104, signed into law April 16, 2015; beginning with 2016, the Secretary shall integrate utilization data information on Physician Compare. This

[5] Kiefe CI, Weissman NW, Allison JJ, Farmer R, Weaver M, Williams OD. Identifying achievable benchmarks of care: concepts and methodology. International Journal of Quality Health Care. 1998 Oct; 10(5):443–7.

[6] Kiefe CI, Allison JJ, Williams O, Person SD, Weaver MT, Weissman NW. Improving Quality Improvement Using Achievable Benchmarks For Physician Feedback: A Randomized Controlled Trial. JAMA. 2001;285(22):2871–2879.

[7] Wessell AM, Liszka HA, Nietert PJ, Jenkins RG, Nemeth LS, Ornstein S. Achievable benchmarks of care for primary care quality indicators in a practice-based research network. American Journal of Medical Quality 2008 Jan–Feb;23(1):39–46.

[8] Top Box score refers to the most favorable response category for a given measure. If the measure has a scale of ''always,'' ''sometimes,'' ''never,'' the Top Box score is ''always'' if this represents the most favorable response. For the CAHPS for PQRS doctor rating, the Top Box score is a rating of 9 or 10.

section of the law discusses data that can help empower people enrolled in Medicare by providing access to information about physician services. These data are very useful to the health care industry and to health care researchers and other stakeholders who can accurately interpret these data and use them in meaningful analysis. These data are less immediately useable in their raw form by the average Medicare consumer. As a result, we propose that the data be added to the downloadable database versus the consumer-focused Web site profile pages. Including these data in the Physician Compare downloadable database provides transparency without taking away from the information of most use to consumers on the main Web site. We solicit comments on this proposal.

(i) Board Certification

Finally, we propose adding additional Board Certification information to the Physician Compare Web site. Board Certification is the process of reviewing and certifying the qualifications of a physician or other health care professional by a board of specialists in the relevant field. We currently include American Board of Medical Specialties (ABMS) data as part of individual EP profiles on Physician Compare. We appreciate that there are additional, well respected boards that are not included in the ABMS data currently available on Physician Compare that represent EPs and specialties represented on the Web site. Such board certification information is of interest to consumers as it provides additional information to use to evaluate and distinguish between EPs on the Web site, which can help in making an informed health care decision. The more data of immediate interest that is included on Physician Compare, the more users will come to the Web site and find quality data that can help them make informed decisions. Specifically, we are now proposing to add to the Web site board certification information from the American Board of Optometry (ABO) and American Osteopathic Association (AOA). Please note we are not endorsing any particular boards. These two specific boards showed interest in being added to the Web site and have demonstrated that they have the data to facilitate inclusion of this information on the Web site. These two boards also fill a gap, as the ABMS does not certify Optometrists and only certain types of DOs are covered by AMBS Osteopathic certification. In general, we will review interest from boards as it is brought to our attention, and if the necessary data are available and appropriate arrangements and agreements can be made to share the needed information with Physician Compare, additional board information could be added to the Web site in future. At this time, however, we are specifically proposing to include ABO and AOA Board Certification information on Physician Compare. We solicit comments on this proposal.

We solicit comments on all proposals. Increasing the measures and data elements for public reporting on Physician Compare at both the individual and group level will help accomplish the Web site's twofold purpose:

- To provide more information for consumers to encourage informed patient choice.
- To create explicit incentives for physicians to maximize performance.

Table 19 summarizes the Physician Compare measure and participation data proposals detailed in this section.

TABLE 19—SUMMARY OF PROPOSED MEASURE AND PARTICIPATION DATA FOR PUBLIC REPORTING

Data collection year*	Publication year*	Data type	Reporting mechanism	Proposed quality measures and data for public reporting
2016	2017	PQRS, PQRS, GPRO, EHR, and Million Hearts.	Web Interface, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the Cardiovascular Prevention measures group proposed under PQRS in support of Million Hearts.
2016	2018	PQRS, PQRS, GPRO.	Web Interface, EHR, Registry, Claims.	Include an indicator for individual EPs and group practices who receive an upward adjustment for the VM.
2016	2017	PQRS, GPRO	Web Interface, EHR, Registry.	All PQRS GPRO measures reported via the Web Interface, EHR, and registry that are available for public reporting for group practices of 2 or more EPs. Publicly report an item-level benchmark, as appropriate.
2016	2017	ACO	Web Interface, Survey Vendor Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs.
2016	2017	CAHPS for PQRS	CMS-Specified Certified CAHPS Vendor.	All CAHPS for PQRS measures for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2016	2017	PQRS	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims. Publicly report an item-level benchmark, as appropriate.
2016	2017	QCDR data	QCDR	All individual EP and group practice QCDR measures.
2016	2017	Utilization data	Claims	Utilization data for individual EPs in the downloadable database.
2016	2017	PQRS, PQRS, GPRO.	Web Interface, EHR, Registry, Claims.	The following data for group practices and individual EPs in the downloadable database: • The VM quality tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality per the VM. • A notation of the payment adjustment received based on the cost and quality tiers. • An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS.

*Note that these data are proposed to be reported annually. The table only provides the first year in which these proposals would begin on an annual basis, and such dates also serve to illustrate the data collection year in relation to the publication year. Therefore, after 2016, 2017 data would be publicly reported in 2018, 2018 data would be publicly reported in 2019, etc.

4. Seeking Public Comment for Possible Future Rulemaking

a. Quality Measures

In addition to these proposals, we seek comment on several new data elements for possible inclusion on the individual EP and group profile pages of Physician Compare. In future years, we will consider expanding public reporting to include additional quality measures. We know there are gaps in the measures currently available for public reporting on Physician Compare. Understanding this, we would like to hear from stakeholders about the types of quality measures that will help us fill these gaps and meet the needs of consumers and stakeholders. Therefore, we seek comment on potential measures that would benefit future public reporting on Physician Compare. We are working to identify possible data sources and we seek comment on the measure concepts, as well as potential specific measures of interest. The quality measures that would be considered for future posting on Physician Compare are those that have been comprehensively vetted and tested, and are trusted by the physician community.

b. Medicare Advantage

We also seek comment on adding Medicare Advantage information to Physician Compare individual EP and group practice profile pages. Specifically, we are seeking comment on adding information on the relevant EP and group practice profile pages about which Medicare Advantage health plans the EP or group accepts and making this information a link to more information about that plan on the Medicare.gov Plan Finder Web site. An increasing number of Medicare clinicians provide services via Medicare Advantage. Medicare Advantage quality data is reported via Plan Finder at the plan level. As a result, physicians and other health care professionals who participate in Medicare Advantage do not have quality measure data available for public reporting on Physician Compare. Adding a link between Physician Compare clinicians participating in Medicare Advantage plans and the associated quality data available for those plans on Plan Finder ensures that consumers have access to all of the quality data available to make an informed health care decision.

c. Value Modifier

We also seek comment on including additional VM cost and quality data on Physician Compare. Specifically, we seek comment on including in future years an indicator for a downward and neutral VM adjustment on group practice and individual EP profile pages. We also seek comment on including the VM quality composite or other VM quality performance data on Physician Compare group practice and individual EP profile pages and/or the Physician Compare downloadable database. Similarly, we seek comment on including the VM cost composite or other VM cost measure data on Physician Compare group practice and individual EP profile pages and/or the downloadable database. These VM quality and cost measures ultimately help determine the payment adjustment and are an indication of whether the individual or group is meeting the Affordable Care Act goals of improving quality while lowering cost. Specifically, including this cost data is consistent with the section 10331(a)(2) of the Affordable Care Act as it is an assessment of efficiency. However, these data are complex and we need time to establish the best method for public reporting and to ensure this information is accurately understood and interpreted by consumers. Therefore, we only seek comment at this time.

d. Open Payments Data

We currently make Open Payments data available at *http://www.cms.gov/openpayments/*. Consumer testing has indicated that these data are of great interest to consumers. Consumers have indicated that this level of transparency is important to them and access to this information on Physician Compare increases their ability to find and evaluate the information. We seek comment about including Open Payments data on individual EP profile pages. Although these data are already publicly available, consumer testing has also indicated that additional context, wording, and data display considerations can help consumers better understand the information. We are now seeking comment on adding these data to Physician Compare; to the extent it is feasible and appropriate. Prior to considering a formal proposal, we can continue to test these data with consumers to establish the context and framing needed to best ensure these data are accurately understood and presented in a way that assists decision making. Therefore, we only seek comment at this time.

e. Measure Stratification

Finally, we seek comment on including individual EP and group practice-level quality measure data stratified by race, ethnicity, and gender on Physician Compare, if feasible and appropriate (*i.e.* statistically appropriate, etc.). By stratification we mean that we will report quality measures for each group of a given category. For example, if we were to report a measure for blood pressure control stratified by sex, we would report a performance score for women and one for men. We also seek comment on potential quality measures, including composite measures, for future postings on Physician Compare that could help consumers and stakeholders monitor trends in health equity. Inclusion of data stratified by race and ethnicity and gender, as well as the inclusion of other measures of health equity would help ensure that HHS is beginning to work to fulfill one of the Affordable Care Act goals of reporting data on race, ethnicity, sex, primary language, and disability status through public postings on HHS Web sites and other dissemination strategies (see ACA Section 4302).

We are specifically seeking comment on these issues. Any data recommended in these areas for public disclosure on Physician Compare would be addressed through separate notice-and-comment rulemaking.

I. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

This section contains the proposed requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments (which ended in 2014) and payment adjustments (which began in 2015) to eligible professionals (EPs) and group practices based on whether they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period or to individual EPs based on whether they satisfactorily participate in a qualified clinical data registry (QCDR). Please note that section 101(b)(2)(A) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) amends section 1848(a)(8)(A) by striking ''2015 or any subsequent year'' and inserting ''each of 2015 through 2018.'' This amendment authorizes the end of the PQRS in 2018 and beginning of a new program, which may incorporate aspects of the PQRS, the Merit-based Incentive Payment System (MIPS).

The proposed requirements primarily focus on our proposals related to the 2018 PQRS payment adjustment, which will be based on an EP's or a group practice's reporting of quality measures

data during the 12-month calendar year reporting period occurring in 2016 (that is, January 1 through December 31, 2016). Please note that, in developing these proposals, we focused on aligning our requirements, to the extent appropriate and feasible, with other quality reporting programs, such as the Medicare Electronic Health Record (EHR) Incentive Program for EPs, the Physician Value-Based Payment Modifier (VM), and the Medicare Shared Savings Program. In previous years, we have made various strides in our ongoing efforts to align the reporting requirements in CMS' quality reporting programs to reduce burden on the EPs and group practices that participate in these programs. We continue to focus on alignment as we develop our proposals for the 2018 PQRS payment adjustment below.

In addition, please note that, in our quality programs, we are beginning to emphasize the reporting of certain types of measures, such as outcome measures, as well as measures within certain NQS domains. Indeed, in its March 2015 report (available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79068*) the Measure Applications Partnership (MAP) has suggested that CMS place an emphasis on higher quality measures, such as functional outcome measures. For example, in the PQRS, we have placed an emphasis on the reporting of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey and cross-cutting measures that promote the health of larger populations and that are applicable to a larger number of patients. As discussed further in this section, we are proposing to require the reporting of the CAHPS for PQRS survey for groups of 25 or more EPs who register to participate in the PQRS Group Practice Reporting Option (GPRO) and select the GPRO web interface as the reporting mechanism. In addition, we are proposing to continue to require the reporting of at least 1 applicable cross-cutting measure if an EP sees at least 1 Medicare patient. Furthermore, when reporting measures via a QCDR, we emphasize the reporting of outcome measures, as well as resource use, patient experience of care, efficiency/appropriate use, or patient safety measures.

The PQRS regulations are specified in § 414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 through 2017 PQRS payment adjustments that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.* In addition, the 2013 PQRS and eRx Experience Report, which provides information about EP participation in PQRS, is available for download at *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS_eRx_Experience_Report_zip.zip.*

1. The Definition of EP for Purposes of Participating in the PQRS

CMS implemented the first PQRS payment adjustment on January 1, 2015. Specifically, EPs who did not satisfactorily report data on quality measures during the 12-month calendar year reporting period occurring in 2013 are receiving a 1.5 percent negative adjustment during CY 2015 on all of the EPs' Part B covered professional services under the Medicare Physician Fee Schedule (PFS). The 2015 PQRS payment adjustment applies to payments for all of the EPs' Part B covered professional services furnished under the PFS. We received many questions surrounding who must participate in the PQRS to avoid the PQRS payment adjustment. As such, we seek to clarify here who is required to participate in the PQRS for purposes of the payment adjustments in this rule.

Please note that there are no hardship or low volume exemptions for the PQRS payment adjustment. All EPs who furnish covered professional services must participate in the PQRS each year by meeting the criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—to avoid the PQRS payment adjustments.

The PQRS payment adjustment applies to EPs who furnish covered professional services. The definition of an EP for purposes of participating in the PQRS is specified in section 1848(k)(3)(B) of the Act. Specifically, the term ''eligible professional'' (EP) means any of the following: (i) A physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)). The term ''covered professional services'' is defined in section 1848(k)(3)(A) of the Act to mean services for which payment is made under, or is based on, the Medicare PFS established under section 1848 and which are furnished by an EP.

EPs in Critical Access Hospitals Billing under Method II (CAH–IIs): We note that EPs in critical access hospitals billing under Method II (CAH–IIs) were previously not able to participate in the PQRS. Due to a change we made in the manner in which EPs in CAH–IIs are reimbursed by Medicare, it is now feasible for EPs in CAH–IIs to participate in the PQRS. EPs in CAH–IIs may participate in the PQRS using ALL reporting mechanisms available, including the claims-based reporting mechanism.

EPs Who Practice in Rural Health Clinics (RHCs) and/or Federally Qualified Health Centers (FQHCs): Services furnished at RHCs and/or FQHCs for which payment is not made under, or based on, the Medicare PFS, or which are not furnished by an EP, are not subject to the PQRS negative payment adjustment. With respect to EPs who furnish covered professional services at RHCs and/or FQHCs that are paid under the Medicare PFS, we note that we are currently unable to assess PQRS participation for these EPs due to the way in which these EPs bill for services under the PFS. Therefore, EPs who practice in RHCs and/or FQHCs would not be subject to the PQRS payment adjustment.

EPs Who Practice in Independent Diagnostic Testing Facilities (IDTFs) and Independent Laboratories (ILs): We note that due to the way IDTF and IL suppliers and their employee EPs are enrolled with Medicare and claims are submitted for services furnished by these suppliers and billed by the IDTF or IL, we are unable to assess PQRS participation for these EPs. Therefore, claims submitted for services performed by EPs who perform services as employee of, or on a reassignment basis to, IDTFs or ILs would not be subject to the PQRS payment adjustment.

2. Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: Claims; qualified registry; EHR (including direct EHR products and EHR data submission vendor products); the GPRO web interface; certified survey vendors, for CAHPS for PQRS survey measures; and the QCDR. Under the existing PQRS regulation, § 414.90(h) through (k) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section contains our proposals to change the QCDR and qualified registry reporting mechanisms. Please note that we are not proposing to make changes to the other PQRS reporting mechanisms.

One of our goals, as indicated in the Affordable Care Act, is to report data on

race, ethnicity, sex, primary language, and disability status. A necessary step toward fulfilling this mission is the collection and reporting of quality data, stratified by race, ethnicity, sex, primary language, and disability status. The agency intends to require the collection of these data elements within each of the PQRS reporting mechanisms. Although we are not proposing in this proposed rule to require the collection of these data elements, we are seeking comments regarding the facilitators and obstacles providers and vendors may face in collecting and reporting these attributes. Additionally, we seek comments on preference for a phased-in approach, perhaps starting with a subset of measures versus a requirement across all possible measures and mechanisms with an adequate timeline for implementation.

a. Proposed Changes to the Requirements for the QCDR

We are required, under section 1848(m)(3)(E)(i) of the Act, to establish requirements for an entity to be considered a QCDR. Such requirements must include a requirement that the entity provide the Secretary with such information, at such times, and in such manner as the Secretary determines necessary to carry out this subsection. Section 1848(m)(3)(E)(iv) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012 (ATRA), requires CMS to consult with interested parties in carrying out this provision. Below, we seek to clarify issues related to QCDR self-nomination, as well as propose a change related to the requirements for an entity to become a QCDR.

Who May Apply to Self-Nominate to Become a QCDR: We have received many questions related to what entities may participate in the PQRS as a QCDR. We note that § 414.90(b) defines a QCDR as a CMS-approved entity that has self-nominated and successfully completed a qualification process showing that it collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A QCDR must perform the following functions:

- Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its EPs have satisfactorily participated in PQRS. A QCDR must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.
- Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.
- Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the QCDR reports on the EP's behalf for purposes of the individual EP's satisfactory participation in the QCDR.
- Possess benchmarking capacity that compares the quality of care an EP provides with other EPs performing the same or similar functions.

We established further details regarding the requirements to become a QCDR in the CYs 2014 and 2015 PFS final rules (78 FR 74467 through 74473 and 79 FR 67779 through 67782). Please note that the requirements we established were not meant to prohibit entities that meet the basic definition of a QCDR outlined in § 414.90(b) from self-nominating to participate in the PQRS as a QCDR. As long as the entity meets the basic definition of a QCDR provided in § 414.90(b), we encourage the entity to self-nominate to become a QCDR.

Self-Nomination Period: We established a deadline for an entity becoming a QCDR to submit a self-nomination statement—specifically, self-nomination statements must be received by CMS by 5:00 p.m., eastern standard time (e.s.t.), on January 31 of the year in which the clinical data registry seeks to be qualified (78 FR 74473). However, we did not specify when the QCDR self-nomination period opens. We received feedback from entities that believed they needed more time to self-nominate. Typically, we open the self-nomination period on January 1 of the year in which the clinical data registry seeks to be qualified. While it is not technically feasible for us to extend the self-nomination deadline past January 31, we will open the QCDR self-nomination period on December 1 of the prior year to allow more time for entities to self-nominate. This would provide entities with an additional month to self-nominate.

Proposed Establishment of a QCDR Entity: In the CY 2014 PFS final rule (78 FR 74467), we established the requirement that, for an entity to become qualified for a given year, the entity must be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). We established this criterion to ensure that an entity seeking to become a QCDR is well-established prior to self-nomination. We have received feedback from entities that this requirement is overly burdensome, as it delays entities otherwise fully capable of becoming a QCDR from participating in the PQRS. To address these concerns while still ensuring that an entity seeking to become a QCDR is well-established, beginning in 2016, we propose to modify this requirement to require the following: For an entity to become qualified for a given year, the entity must be in existence as of January 1 the year for which the entity seeks to become a QCDR (for example, January 1, 2016, to be eligible to participate for purposes of data collected in 2016). We invite public comment on this proposal.

Attestation Statements for QCDRs Submitting Quality Measures Data during Submission: In the CY 2014 PFS final rule, to ensure that the data provided by the QCDR is correct, we established the requirement that QCDRs provide CMS a signed, written attestation statement via email which states that the quality measure results and any and all data, including numerator and denominator data, provided to CMS are accurate and complete (78 FR 74472). In lieu of submitting an attestation statement via email, beginning in 2016, we propose to allow QCDRs to attest during the data submission period that the quality measure results and any and all data including numerator and denominator data provided to CMS will be accurate and complete using a web-based check box mechanism available at *https://www.qualitynet.org/portal/server.pt/community/pqri_home/212.* We believe it is less burdensome for QCDRs to check a box acknowledging and attesting to the accuracy of the data they provide, rather than having to email a statement to CMS. Please note that, if this proposal is finalized, QCDRs will no longer be able to submit this attestation statement via email. We invite public comment on this proposal.

In addition, we noted in the CY 2015 PFS final rule (79 FR 67903) that entities wishing to become QCDRs would have until March 31 of the year in which it seeks to become a QCDR to submit measure information the entity intends to report for the year, which included submitting the measure specifications for non-PQRS measures the QCDR intends to report for the year. However, we have experienced issues related to the measures data we received during the 2013 reporting year. These issues prompt us to more closely analyze the measures for which an entity intends to report as a QCDR. Therefore, so that we may vet and analyze these vendors to determine whether they are fully ready to be qualified to participate in the PQRS as a QCDR, we propose to require that all

other documents that are necessary to analyze the vendor for qualification be provided to CMS at the time of self-nomination, that is, by no later than January 31 of the year in which the vendor intends to participate in the PQRS as a QCDR (that is, January 31, 2016 to participate as a QCDR for the reporting periods occurring in 2016). This includes, but is not limited to, submission of the vendor's data validation plan as well as the measure specifications for the non-PQRS measures the entity intends to report. In addition, please note that after the entity submits this information on January 31, it cannot later change any of the information it submitted to us for purposes of qualification. For example, once an entity submits measure specifications on non-PQRS measures, it cannot later modify the measures specifications the entity submitted. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

Data Validation Requirements: A validation strategy details how the qualified registry will determine whether EPs and GPRO group practices have submitted data accurately and satisfactorily on the minimum number of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the qualified registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. The current guidance on validation strategy is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_RegistryVendorCriteria.pdf.* In analyzing our requirements, we believe adding the following additional requirements will help mitigate issues that may occur when collecting, calculating, and submitting quality measures data to CMS. Therefore, we propose that, beginning in 2016, a QCDR must provide the following information to CMS at the time of self-nomination to ensure that QCDR data is valid:

- Organization Name (Specify Sponsoring Organization name and qualified registry name if the two are different).
- Program Year.
- Vendor Type (for example, qualified registry).
- Provide the method(s) by which the entity obtains data from its customers: claims, web-based tool, practice management system, EHR, other (please explain). If a combination of methods (Claims, Web Based Tool, Practice Management System, EHR, and/or other) is utilized, please state which method(s) the entity utilizes to collect reporting numerator and denominator data.
- Indicate the method the entity will use to verify the accuracy of each Tax Identification Number (TIN) and National Provider Identifier's (NPI) it is intending to submit (that is, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).
- Describe the method that the entity will use to accurately calculate both reporting rates and performance rates for measures and measures groups based on the appropriate measure type and specification. For composite measures or measures with multiple performance rates, the entity must provide us with the methodology the entity uses for these composite measures and measures with multiple performance rates.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to CMS. Periodic examinations may be completed to compare patient record data with submitted data and/or ensure PQRS measures were accurately reported based on the appropriate Measure Specifications (that is, accuracy of numerator, denominator, and exclusion criteria).
- If applicable, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the TIN/NPIs be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Define a process for completing a detailed audit if the qualified registry's validation reveals inaccuracy and describe how this information will be conveyed to CMS.

QCDRs must perform the validation outlined in the validation strategy and send evidence of successful results to CMS for data collected in the reporting periods occurring in 2016. The Data Validation Execution Report must be sent via email to the QualityNet Help Desk at *Qnetsupport@sdps.org* by 5:00 p.m. ET on June 30, 2016. The email subject should be ''PY2015 Qualified Registry Data Validation Execution Report.''

Submission of Quality Measures Data for Group Practices: Section 101(d)(1)(B) of the MACRA amends section 1848(m)(3)(D) of the Act by inserting ''and, for 2016 and subsequent years, subparagraph (A) or (C)'' after ''subparagraph (A)''. This change authorizes CMS to create an option for EPs participating in the GPRO to report quality measures via a QCDR. As such, in addition to being able to submit quality measures data for individual EPs, we propose that QCDRs also have the ability to submit quality measures data for group practices.

b. Proposed Changes to the Requirements for Qualified Registries

Attestation Statements for Registries Submitting Quality Measures Data: In the CY 2013 PFS final rule, we finalized the following requirement to ensure that the data provided by a registry is correct: We required that the registry provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete for each year the registry submits quality measures data to CMS (77 FR 69180). In lieu of submitting an attestation statement via email or mail, beginning in 2016, we propose to allow registries to attest during the submission period that the quality measure results and any and all data including numerator and denominator data provided to CMS will be accurate and complete using a web-based check box mechanism available at *https://www.qualitynet.org/portal/server.pt/community/pqri_home/212.* We believe it is less burdensome for registries to check a box acknowledging and attesting to the accuracy of the data they provide, rather than having to email a statement to CMS. Please note that, if this proposal is finalized, qualified registries will no longer be able to submit this attestation statement via email or mail. We invite public comment on this proposal.

In addition, so that we may vet and analyze these vendors to determine whether they are fully ready to be qualified to participate in the PQRS as a qualified registry, we propose to require that all other documents that are necessary to analyze the vendor for qualification be provided to CMS at the time of self-nomination, that is, by no later than January 31 of the year in which the vendor intends to participate in the PQRS as a qualified registry (that is, January 31, 2016 to participate as a qualified registry for the reporting periods occurring in 2016). This

includes, but is not limited to, submission of the vendor's data validation plan. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

Data Validation Requirements: A validation strategy details how the qualified registry will determine whether EPs and GPRO group practices have submitted accurately and satisfactorily on the minimum number of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the qualified registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. The current guidance on validation strategy is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_RegistryVendorCriteria.pdf.* In analyzing our requirements, we believe adding the following additional requirements will help mitigate issues that may occur when collecting, calculating, and submitting quality measures data to CMS. Therefore, we propose that, beginning in 2016, a QCDR must provide the following information to CMS at the time of self-nomination to ensure that data submitted by a qualified registry is valid:

- Organization Name (specify the sponsoring entity name and qualified registry name if the two are different).
- Program Year.
- Vendor Type (for example, qualified registry).
- Provide the method(s) by which the entity obtains data from its customers: claims, web-based tool, practice management system, EHR, other (please explain). If a combination of methods (Claims, Web Based Tool, Practice Management System, EHR, and/or other) is utilized, please state which method(s) the entity utilizes to collect its reporting numerator and denominator data.
- Indicate the method the entity will use to verify the accuracy of each TIN and NPI it is intending to submit (that is, NPPES, CMS claims, tax documentation).
- Describe how the entity will verify that EPs or group practices report on at least 1 measure contained in the cross-cutting measure set if the EP or group practice sees at least 1 Medicare patient in a face-to-face encounter. Describe how the entity will verify that the data provided is complete and contains the entire cohort of data.
- Describe the method that the entity will use to accurately calculate both reporting rates and performance rates for measures and measures groups based on the appropriate measure type and specification.
- Describe the method the entity will use to verify that only the measures in the applicable PQRS Claims and Registry Individual Measure Specifications (that is, the 2016 PQRS Claims and Registry Individual Measure Specifications for data submitted for reporting periods occurring in 2016) and applicable PQRS Claims and Registry Measures Groups Specifications (that is, the 2016 PQRS Claims and Registry Measures Groups Specifications for data submitted for reporting periods occurring in 2016) are utilized for submission.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to CMS. Periodic examinations may be completed to compare patient record data with submitted data and/or ensure PQRS measures were accurately reported based on the appropriate Measure Specifications (that is, accuracy of numerator, denominator, and exclusion criteria).
- If applicable, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the TIN/NPIs be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Define a process for completing a detailed audit if the qualified registry's validation reveals inaccuracy and describe how this information will be conveyed to CMS.
- Registries must maintain the ability to randomly request and receive documentation from providers to verify accuracy of data. Registries must also provide CMS access to review the Medicare beneficiary data on which the applicable PQRS registry-based submissions are based or provide to CMS a copy of the actual data (if requested for validation purposes).

Qualified registries must perform the validation outlined in the validation strategy and send evidence of successful results to CMS for data collected for the applicable reporting periods. The Data Validation Execution Report must be sent via email to the QualityNet Help Desk at *Qnetsupport@sdps.org* by 5:00 p.m. ET on June 30 of the year in which the reporting period occurs (that is, June 30, 2016 for reporting periods occurring in 2016). The email subject should be ''PY2015 Qualified Registry Data Validation Execution Report.''

c. Auditing of Entities Submitting PQRS Quality Measures Data

We are in the process of auditing PQRS participants, including vendors who submit quality measures data. We believe it is essential for vendors to corporate with this audit process. In order to ensure that CMS has adequate information to perform an audit of a vendor, we are proposing that, beginning in 2016, any vendor submitting quality measures data for the PQRS (for example, entities participating the PQRS as a qualified registry, QCDR, direct EHR, or DSV) comply with the following requirements:

- The vendor make available to CMS the contact information of each EP on behalf of whom it submits data. The contact information will include, at a minimum, the EP practice's phone number, address, and, if applicable email.
- The vendor must retain all data submitted to CMS for the PQRS program for a minimum of seven years.

We invite public comment on these proposals.

3. Proposed Criteria for the Satisfactory Reporting for Individual EPs for the 2018 PQRS Payment Adjustment

Section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act, provides that for covered professional services furnished by an EP during 2015 or any subsequent year, if the EP does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

a. Proposed Criterion for the Satisfactory Reporting of Individual Quality Measures via Claims and Registry for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criteria for satisfactory reporting for the submission of individual quality measures via

claims and registry for 2017 PQRS payment adjustment (see Table 50 at 79 FR 67796): For the applicable 12-month reporting period, the EP would report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the EP, report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an EP who reports fewer than 9 measures covering less than 3 NQS domains via the claims- or registry-based reporting mechanism, the EP would be subject to the measure application validity (MAV) process, which would allow us to determine whether the EP should have reported quality data codes for additional measures. To meet the criteria for the 2017 PQRS payment adjustment, we added the following requirement: Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, as we propose to define that term below, the EP would report on at least 1 measure contained in the PQRS cross-cutting measure set.

To be consistent with the satisfactory reporting criterion we finalized for the 2017 PQRS payment adjustment, we are proposing to amend § 414.90(j) to specify the same criterion for individual EPs reporting via claims and registry for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, as we propose to define that term below, the EP would report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

For what defines a ''face-to-face'' encounter, for purposes of proposing to require reporting of at least 1 cross-cutting measure, we propose to determine whether an EP had a ''face-to-face'' encounter by assessing whether the EP billed for services under the PFS that are associated with face-to-face encounters, such as whether an EP billed general office visit codes, outpatient visits, and surgical procedures. We would not include telehealth visits as face-to-face encounters for purposes of the proposal requiring reporting of at least 1 cross-cutting measure. For our current list of face-to-face encounter codes for the requirement to report a cross-cutting measure, please see *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/FacetoFace_Encounter_CodeList_01302015.zip*.

In addition, we understand that there may be instances where an EP may not have at least 9 measures applicable to an EP's practice. In this instance, like the criterion we finalized for the 2017 payment adjustment (*see* Table 50 at 79 FR 67796), an EP reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the EP reports on each measure that is applicable to the EP's practice. If an EP reports on less than 9 measures, the EP would be subject to the MAV process, which would allow us to determine whether an EP should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether an EP should have reported on any of the PQRS cross-cutting measures. The MAV process we are proposing to implement for claims and registry is the same process that was established for reporting periods occurring in 2015 for the 2017 PQRS payment adjustment. For more information on the claims and registry MAV process, please visit the measures section of the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html*.

We seek public comment on our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment.

b. Proposed Criterion for Satisfactory Reporting of Individual Quality Measures via EHR for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criterion for the satisfactory reporting for individual EPs reporting individual measures via a direct EHR product or an EHR data submission vendor product for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796): For the applicable 12-month reporting period, report at least 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP must report all of the measures for which there is Medicare patient data. Although all-payer data may be included in the file, an EP must report on at least 1 measure for which there is Medicare patient data for their submission to be considered for PQRS.

To be consistent with the criterion we finalized for the 2017 PQRS payment adjustment, as well as to continue to align with the final criterion for meeting the clinical quality measure (CQM) component of achieving meaningful use under the Medicare EHR Incentive Program, we are proposing to amend § 414.90(j) to specify the criterion for the satisfactory reporting for individual EPs to report individual measures via a direct EHR product or an EHR data submission vendor product for the 2018 PQRS payment adjustment. Specifically, the EP would report at least 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data.

We seek public comment on this proposal.

c. Proposed Criterion for Satisfactory Reporting of Measures Groups via Registry for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criterion for the satisfactory reporting for individual EPs to report measures groups via registry for the 2017 PQRS payment adjustment (see Table 50 at 79 FR 67796): For the applicable 12-month reporting period, report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

To be consistent with the criterion we finalized for the 2017 PQRS payment adjustment, we are proposing to amend § 414.90(j) to specify the same criterion for the satisfactory reporting for individual EPs to report measures groups via registry for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 1 measures group AND report each measures group for at

least 20 patients, the majority (11 patients) of which would be required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate would not be counted.

We seek public comment on our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment.

4. Satisfactory Participation in a QCDR by Individual EPs

Section 601(b) of the ATRA amended section 1848(m)(3) of the Act, by redesignating subparagraph (D) as subparagraph (F) and adding new subparagraphs (D) and (E), to provide for a new standard for individual EPs to satisfy the PQRS beginning in 2014, based on satisfactory participation in a QCDR.

a. Proposed Criterion for the Satisfactory Participation for Individual EPs in a QCDR for the 2018 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an EP during 2015 or any subsequent year, if the EP does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual EP as satisfactorily submitting data on quality measures under section 1848(m)(3)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the EP is satisfactorily participating in a QCDR for the year. ''Satisfactory participation'' is a relatively new standard under the PQRS and is an analogous standard to the standard of ''satisfactory reporting'' data on covered professional services that EPs who report through other mechanisms must meet to avoid the PQRS payment adjustment. Currently, § 414.90(e)(2) states that individual EPs must be treated as satisfactorily reporting data on quality measures if the individual EP satisfactorily participates in a QCDR.

To be consistent with the number of measures reported for the satisfactory participation criterion we finalized for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796), for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to revise § 414.90(k) to use the same criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

We seek public comment on this proposal.

5. Proposed Criteria for Satisfactory Reporting for Group Practices Participating in the GPRO

In lieu of reporting measures under section 1848(k)(2)(C) of the Act, section 1848(m)(3)(C) of the Act provides the Secretary with the authority to establish and have in place a process under which EPs in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures. Accordingly, this section III.K.4 contains our proposed satisfactory reporting criteria for group practices participating in the GPRO. Please note that, for a group practice to participate in the PQRS GPRO in lieu of participating as individual EPs, a group practice is required to register to participate in the PQRS GPRO. For more information on GPRO participation, please visit *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Group_Practice_Reporting_Option.html.* For more information on registration, please visit *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Self-Nomination-Registration.html.*

a. The CAHPS for PQRS Survey

In the CY 2015 PFS final rule, we required group practices of 100 or more EPs that register to participate in the GPRO for 2015 reporting to select a CMS-certified survey vendor to report the CAHPS for PQRS survey, regardless of the reporting mechanism the group practice chooses (79 FR 67794). We also stated that group practices would bear the cost of administering the CAHPS for PQRS survey. To collect CAHPS for PQRS data from smaller groups, for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to require group practices of 25 or more EPs that register to participate in the GPRO and select the GPRO web interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRS. We believe this proposal is consistent with our effort to collect CAHPS for PQRS data whenever possible. However, we are excluding from this proposal group practices that report measures using the qualified registry, EHR, and QCDR reporting mechanisms, because we have discovered that certain group practices reporting through these mechanisms may be highly specialized or otherwise unable to report CAHPS for PQRS. Please note that we are still proposing to keep CAHPS for PQRS reporting as an option for all group practices. We note that all group practices that would be required to report or voluntarily elect to report CAHPS for PQRS would need to continue to select and pay for a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. We invite public comment on this proposal.

We understand that this proposed requirement may cause concern for smaller group practices who choose to participate in the PQRS via the GPRO web interface, particularly those who have not yet administered the CAHPS for PQRS survey (as we introduced reporting of the CAHPS for PQRS survey in 2014) or those group practices who do not believe the CAHPS for PQRS survey applies to their practice. Since the introduction of the CAHPS for PQRS survey, we have received questions as on when the CAHPS for PQRS survey applies to a group practice. In this section below, we seek to clarify questions we have received regarding the administration of the CAHPS for PQRS survey. We note that this proposed requirement would only apply to group practices of 25 or more EPs for whom CAHPS for PQRS applies.

In addition, we note that we finalized a 12-month reporting period for the administration of the CAHPS for PQRS survey. However, as group practice s have until June of the applicable reporting period (that is, June 30, 2016 for the 12-month reporting period occurring January 1, 2016–December 31, 2016) to elect to participate in the PQRS as a GPRO and administer CAHPS for PQRS, it is not technically feasible for us to collect data for purposes of CAHPS for PQRS until the close of the GPRO

registration period. As such, the administration of the CAHPS for PQRS survey only contains 6-months of data. We do not believe this significantly alters the administration of CAHPS for PQRS, as we believe that 6-months of data provides an adequate sample of the 12-month reporting period.

The CAHPS for PQRS survey consists of the core CAHPS Clinician & Group Survey developed by AHRQ, plus additional survey questions to meet CMS' information and program needs. The survey questions are aggregated into 12 content domains called Summary Survey Measures (SSMs). SSMs contain one or more survey questions. The CAHPS for PQRS survey consists of the following survey measures: (1) Getting timely care, appointments, & information; (2) How well your providers communicate; (3) Patient's rating of provider; (4) Access to specialists; (5) Health promotion and education; (6) Shared decision making; (7) Health status & functional status; (8) Courteous & helpful office staff; (9) Care coordination; (10) Between visit communication; (11) Helping you take medications as directed; and (12) Stewardship of patient resources. For the CAHPS for PQRS survey to apply to a group practice, the group practice must have an applicable focal provider as well as meet the minimum beneficiary sample for the CAHPS for PQRS survey.

Identifying Focal Providers: Which provider does the survey ask about? The provider named in the survey provided the beneficiary with the plurality of the beneficiary's primary care services delivered by the group practice. Plurality of care is based on the number of primary care service visits to a provider. The provider named in the survey can be a physician (primary care provider or specialist), nurse practitioner (NP), physician's assistant (PA), or clinical nurse specialist (CNS).

Exclusion Criteria for Focal Providers: Several specialty types are excluded from selection as focal provider such as anesthesiology, pathology, psychiatry optometry, diagnostic radiology, chiropractic, podiatry, audiology, physical therapy, occupational therapy, clinical psychology, diet/nutrition, emergency medicine, addiction medicine, critical care, and clinical social work. Hospitalists are also excluded from selection as a focal provider.

Beneficiary Sample Selection: CMS retrospectively assigns Medicare beneficiaries to your group practice based on whether the group provided a wide range of primary care services. Assigned beneficiaries must have a plurality of their primary care claims delivered by the group practice. Assigned beneficiaries have at least one month of both Part A and Part B enrollment and no months of Part A only enrollment or Part B only enrollment. Assigned beneficiaries cannot have any months of enrollment in a Medicare Advantage plan. Regardless of the number of EPs, some group practices may not have a sufficient number of assigned beneficiaries to participate in the CAHPS for PQRS survey.

We draw a sample of Medicare beneficiaries assigned to a practice. For practices with 100 or more eligible providers, the desired sample is 860, and the minimum sample is 416. For practices with 25 to 99 eligible providers, the desired sample is 860, and the minimum sample is 255. For practices with 2 to 24 eligible providers, the desired sample is 860, and the minimum sample is 125. The following beneficiaries are excluded in the practice's patient sample: Beneficiaries under age 18 at the time of the sample draw; beneficiaries known to be institutionalized at the time of the sample draw; and beneficiaries with no eligible focal provider. For more information on CAHPS for PQRS, please visit the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/CMS-Certified-Survey-Vendor.html*.

b. Proposed Criteria for Satisfactory Reporting on PQRS Quality Measures via the GPRO Web Interface for the 2018 PQRS Payment Adjustment

Under our authority specified for the group practice reporting requirements under section 1848(m)(3)(C) of the Act—to be consistent with the criterion we finalized for the satisfactory reporting of PQRS quality measures for group practices registered to participate in the GPRO for the 2017 PQRS payment adjustment using the GPRO web interface (see Table 51 at 79 FR 67797)—we propose to amend § 414.90(j) to specify criteria for the satisfactory reporting of PQRS quality measures for group practices registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the GPRO web interface for groups practices of 25 or more EPs for which the CAHPS for PQRS survey does not apply. Specifically, the group practice would report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. A group practice would be required to report on at least 1 measure in the GPRO web interface. Although the criteria proposed above are specified for groups practices of 25 or more EPs, please note that, given our proposal below to require that group practices of 25 or more EPs report the CAHPS for PQRS survey, the criteria proposed above would apply to a group practices of 25 or more EPs only if the CAHPS for PQRS survey does not apply to the group practice.

Furthermore, similar to the criteria we established for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797), as we specified in section III.K.4.a., we propose to require that group practices of 25 or more EPs who elect to report quality measures via the GPRO web interface report the CAHPS for PQRS survey, if applicable. Therefore, similar to the criteria we established for the 2017 PQRS payment adjustment in accordance with section 1848(m)(3)(C) of the Act (see Table 51 at 79 FR 67797), we propose to amend § 414.90(j) to specify criteria for the satisfactory reporting of PQRS quality measures for group practices of 25 or more EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the GPRO web interface and for which the CAHPS for PQRS survey applies. Specifically, if a group practice chooses to use the GPRO web interface in conjunction with reporting the CAHPS for PQRS survey measures, we propose to specify the criterion for satisfactory reporting for the 2018 PQRS payment adjustment. For the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor. In addition, the group practice would report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each

module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

For assignment of patients for group practices reporting via the GPRO web interface, in previous years, we have aligned with the Medicare Shared Savings Program methodology of beneficiary assignment (see 77 FR 69195). However, for the 2017 PQRS payment adjustment, we used a beneficiary attribution methodology utilized within the VM for the claims-based quality measures and cost measures that is slightly different from the Medicare Shared Savings Program assignment methodology that applied in 2015, namely (1) eliminating the primary care service pre-step that is statutorily required for the Shared Savings Program and (2) including NPs, PAs, and CNSs in step 1 rather than in step 2 of the attribution process. We believe that aligning with the VM's method of attribution is appropriate, as the VM is directly tied to participation in the PQRS (79 FR 67790). Therefore, to be consistent with the sampling methodology we used for the 2017 PQRS payment adjustment, we propose to continue using the attribution methodology used for the VM for the GPRO web interface beneficiary assignment methodology for the 2018 PQRS payment adjustment and future years.

As we clarified in the CY 2015 PFS final rule with comment period (79 FR 67790), if a group practice has no Medicare patients for which any of the GPRO measures are applicable, the group practice will not meet the criteria for satisfactory reporting using the GPRO web interface. Therefore, to meet the criteria for satisfactory reporting using the GPRO web interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable GPRO web interface measures. If a group practice does not typically see Medicare patients for which the GPRO web interface measures are applicable, or if the group practice does not have adequate billing history for Medicare patients to be used for assignment and sampling of Medicare patients into the GPRO web interface, we advise the group practice to participate in the PQRS via another reporting mechanism.

We invite public comment on these proposals.

c. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via *Registry* for the 2018 PQRS Payment Adjustment

We finalized the following satisfactory reporting criteria for the submission of individual quality measures via registry for group practices of 2–99 EPs in the GPRO for the 2017 PQRS payment adjustment (see Table 51 at 79 FR 67797): Report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report up to 8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

Consistent with the group practice reporting criteria we finalized for the 2017 PQRS payment adjustment in accordance with section 1848(m)(3)(C) of the Act, for those group practices that choose to report using a qualified registry, we propose to amend § 414.90(j) to specify satisfactory reporting criteria via qualified registry for group practices of 2+ EPs who select to participate in the GPRO for the 2018 PQRS payment adjustment. Specifically, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice would report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice has an EP that sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If the group practice reports on less than 9 measures covering at least 3 NQS domains, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

In addition, if a group practice of 2+ EPs chooses instead to use a qualified registry in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the non-CAHPS for PQRS measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would be required to report on at least 1 measure in the PQRS cross-cutting measure set. We note that this proposed option to report 6 additional measures, including at least 1 cross-cutting measure if a group practice sees at least 1 Medicare patient in a face-to-face encounter, is consistent with the proposed criterion for satisfactory reporting for the 2018 PQRS payment adjustment via qualified registry.

As with individual reporting, we understand that there may be instances where a group practice may not have at least 9 measures applicable to a group practice's practice. In this instance, like the criterion we finalized for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797), a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via registry if the group practice reports on each measure that is applicable to the group practice's practice. If a group practice reports on less than 9 measures, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported quality data codes for additional measures and/or measures covering additional NQS domains. In addition, if a group practice does not report on at least 1 cross-cutting measure and the group practice has at least 1 EP who sees at least 1 Medicare patient in a face-to-face encounter, the MAV will also allow us to determine whether a group practice should have reported on any of the PQRS cross-cutting measures. The MAV process we are proposing to implement for registry reporting is a similar process that was established for reporting periods occurring in 2015 for the 2017 PQRS payment adjustment. However, please note that the MAV process for the 2018 PQRS payment adjustment will now allow us to determine whether a group practice should have reported on at least 1 cross-cutting measure. For more information on the registry MAV process, please visit *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.*

We invite public comment on these proposals.

d. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via *EHR* for the 2018 PQRS Payment Adjustment

For EHR reporting, consistent with the criterion finalized for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797) that aligns with the criteria established for meeting the CQM component of meaningful use under the Medicare EHR Incentive Program and in accordance with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using an EHR, we propose to amend § 414.90(j) to specify satisfactory reporting criteria via a direct EHR product or an EHR data submission vendor product for group practices of 2+ EPs who select to participate in the GPRO for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

In addition, if a group practice of 2+ EPs chooses instead to use a direct EHR product or EHR data submission vendor in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all applicable measures. Of the non-CAHPS for PQRS measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data. We note that this proposed option to report 6 additional measures is consistent with the proposed criterion for satisfactory reporting for the 2018 PQRS payment adjustment via EHR without CAHPS for PQRS, since both criteria assess a total of 3 domains.

We invite public comment on these proposals.

e. Satisfactory Participation in a QCDR for Group Practices Registered To Participate in the GPRO via a *QCDR* for the 2018 PQRS Payment Adjustment

Section 101(d)(1)(B) of the MACRA amends section 1848(m)(3)(D) of the Act by inserting ''and, for 2016 and subsequent years, subparagraph (A) or (C)'' after ''subparagraph (A)''. This change authorizes CMS to create an option for EPs participating in the GPRO to report quality measures via a QCDR.

As such, please note that we are modifying § 414.90(k) to indicate that group practices may also use a QCDR to participate in the PQRS.

f. Proposed Reporting Period for the Satisfactory Participation by Individual EPs in a QCDR for the 2018 PQRS Payment Adjustment

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012 and further amended by MACRA, authorizes the Secretary to treat a group practice as satisfactorily submitting data on quality measures under section 1848(m)(3)(A) of the Act if the group practice is satisfactorily participating in a QCDR for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with the reporting period applicable to individual EPs who participate in the PQRS via a QCDR, we propose to revise § 414.90(k) to specify a 12-month, CY reporting period from January 1, 2016 through December 31, 2016 for group practices participating in the GPRO to satisfactorily participate in a QCDR for purposes of the 2018 PQRS payment adjustment. We are proposing a 12-month reporting period. Based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting periods. In addition, we believe a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the group practice in the QCDR. We invite public comment on the proposed 12-month, CY 2016 reporting period for the satisfactory participation of group practices in a QCDR for the 2018 PQRS payment adjustment.

g. Proposed Criteria for Satisfactory Participation in a QCDR for Group Practices Registered To Participate in the GPRO via a *QCDR* for the 2018 PQRS Payment Adjustment

To be consistent with individual reporting criteria that we finalized for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796) as well as our proposed individual reporting criteria for the 2018 PQRS payment adjustment, for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to amend § 414.90(j) to use the same criterion for group practices as individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

Tables 20 and 21 reflect our proposed criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—for the 2018 PQRS payment adjustment:

TABLE 20—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND EHRS AND SATISFACTORY PARTICIPATION CRITERION IN QCDRS

Reporting period	Measure type	Reporting mechanism	Satisfactory reporting/satisfactory participation criteria
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Claims	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	Measures Groups	Qualified Registry	Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	Qualified Clinical Data Registry (QCDR).	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	25+ EPs (if CAHPS for PQRS does not apply).	Individual GPRO Measures in the GPRO Web Interface.	GPRO Web Interface.	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	25+ EPs (if CAHPS for PQRS applies).	Individual GPRO Measures in the GPRO Web Interface + CAHPS for PQRS.	GPRO Web Interface + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data. Please note that, if the CAHPS for PQRS survey is applicable to a group practice who reports quality measures via the GPRO web interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the GPRO web interface measures.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures.	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Qualified Registry + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the PQRS cross-cutting measure set.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures.	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is Medicare patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	Qualified Clinical Data Registry (QCDR).	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

6. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2016 and Beyond for Individual EPs and Group Practices

Annually, we solicit or ''Call for Measures'' from the public for possible inclusion in the PQRS. During the Call for Measures, we request measures for inclusion in PQRS that meet the following statutory and other criteria.

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual EPs and group practices under the PQRS. Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act, which is currently the National Quality Forum (NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, the Secretary shall ensure that EPs have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish. The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) and are silent as to how the measures that are submitted to the NQF for endorsement are developed.

The steps for developing measures applicable to physicians and other EPs prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be special restrictions on the type or make-up of the organizations carrying out this process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the Secretary establish a pre-rulemaking process under which certain steps occur for the selection of certain categories of quality and efficiency measures, one of which is that the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of such measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. In accordance with section 1890A(a)(1) of the Act, the NQF convened multi-stakeholder groups by creating the MAP. Section 1890A(a)(2) of the Act requires that the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. The NQF must provide CMS with the MAP's input on the selection of measures by February 1st of each year. The lists of measures under consideration for selection through rulemaking in 2015 are available at *http://www.qualityforum.org/map/.*

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- Measures that are not duplicative of another existing or proposed measure.
- Measures that are further along in development than a measure concept.
- We are not accepting claims-based-only reporting measures in this process.
- Measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that include the NQS domain for care coordination and communication.
- Measures that include the NQS domain for patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

a. Proposed PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our proposals for the inclusion or removal of measures in PQRS for 2016 and beyond. We are classifying all proposed measures against six domains based on the NQS's six priorities, as follows:

(1) Patient Safety. These are measures that reflect the safe delivery of clinical services in all healthcare settings. These measures may address a structure or process that is designed to reduce risk in the delivery of healthcare or measure the occurrence of an untoward outcome such as adverse events and complications of procedures or other interventions.

(2) Person and Caregiver-Centered Experience and Outcomes. These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level. These are measures of organizational structures or processes that foster both the inclusion of persons and family members as active members of the health care team and collaborative partnerships with providers and provider organizations or can be measures of patient-reported experiences and outcomes that reflect greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(3) Communication and Care Coordination. These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication. They may also be measures that reflect outcomes of successful coordination of care.

(4) Effective Clinical Care. These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states.

(5) Community/Population Health. These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. They may be measures of processes focused on primary prevention of disease or general screening for early detection of disease unrelated to a current or prior condition.

(6) Efficiency and Cost Reduction. These are measures that reflect efforts to lower costs and to significantly improve outcomes and reduce errors. These are measures of cost, resource use and appropriate use of healthcare resources or inefficiencies in healthcare delivery.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2016 and beyond, please note that detailed measure specifications, including the measure's title, for the proposed individual PQRS quality measures for 2016 and beyond may have been updated or modified during the NQF endorsement process or for other reasons.

In addition, due to our desire to align measure titles with the measure titles that have been finalized for 2013, 2014, 2015 reporting, and potentially subsequent years of the Medicare EHR Incentive Program, we note that the measure titles for measures available for reporting via EHR-based reporting mechanisms may change. To the extent that the Medicare EHR Incentive Program updates its measure titles to include version numbers (see 77 FR 13744), we will use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program. We will continue to work toward complete alignment of measure specifications across programs whenever possible.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. Further, we believe that non-substantive maintenance changes of this type do not trigger the same agency obligations under the Administrative Procedure Act.

In the CY 2013 PFS final rule with comment period, we finalized our proposal providing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantively change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program (77 FR 69207). We believe this adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that change an endorsed measure such that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

We are not the measure steward for most of the measures available for reporting under the PQRS. We rely on outside measure stewards and developers to maintain these measures. In Table 25, we are proposing that certain measures be removed from the PQRS measure set due to the measure steward indicating that it will not be able to maintain the measure. We note that this proposal is contingent upon the measure steward not being able to maintain the measure. Should we learn that a certain measure steward is able to maintain the measure, or that another entity is able to maintain the measure in a manner that allows the measure to be available for reporting under the PQRS for the CY 2018 PQRS payment adjustment, we propose to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. In addition, if, after the display of this proposed rule and before the display of the CY 2016 PFS final rule, we discover additional measures within the current PQRS measure set that a measure steward can no longer maintain, we propose to remove these measures from reporting for the PQRS beginning in 2016. We will discuss any such instances in the CY 2016 PFS final rule with comment period.

In addition, we note that we have received feedback from stakeholders, particularly first-time participants who find it difficult to understand which measures are applicable to their

particular practice. In an effort to aide EPs and group practices to determine what measures best fit their practice, and in collaboration with specialty societies, we are beginning to group our final measures available for reporting according to specialty. The current listing of our measures by specialty can be found on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. Please note that these groups of measures are meant to provide guidance to those EPs seeking to determine what measures to report. EPs are not required to report measures according to these suggested groups of measures. As measures are adopted or revised, we will continue to update these groups to reflect the measures available under the PQRS, as well as add more specialties.

In Tables 22 through 30, we propose changes to the PQRS measures set. The current PQRS measures list is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PQRS_2015_Measure-List_111014.zip*.

b. Proposed Cross-Cutting Measures for 2016 Reporting and Beyond

In the CY 2015 PFS final rule with comment period, we finalized a set of 19 cross-cutting measures for reporting in the PQRS for 2015 and beyond (see Table 52 at 79 FR 67801). The current PQRS cross-cutting measure set is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Crosscutting Measures_12172014.pdf*. In Table 22, we propose the following measures to be added to the current PQRS cross-cutting measure set. Please note that our rationale for proposing each of these measures is found below the measure description.

TABLE 22: Proposed Individual Quality Cross-Cutting Measures for the PQRS to be Available for Satisfactory Reporting via Claims, Registry, and HER beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Other Quality Reporting Programs
2152/ N/A	N/A	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user. **Rationale**: This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it represents a screening assessment for unhealthy alcohol use that most EPs may perform, assess, and document to ensure maintenance for this risk, and is applicable to most Medicare adult patients.	American Medical Association – Physician Consortium for Performance Improvement	
2372/ 112	125v3	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims, registry, EHR, GPRO and measures group in the PQRS in the CY 2013 PFS final rule (77 FR 69227). This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it represents a screening assessment for breast cancer that most EPs may perform, assess, and document to ensure maintenance for this risk, and is applicable to most Medicare female adult patients.	National Committee for Quality Assurance	ACO/ MU2
0101/ 154	N/A	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69232). In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting. This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 PFS as it is applicable to a variety of physican specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.	National Committee for Quality Assurance/ American Medical Association – Physician Consortium for Performance Improvement	
0101/ 155	N/A	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69232). In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting. This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it is applicable to a variety of physican specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.	National Committee for Quality Assurance/ American Medical Association – Physician Consortium for Performance Improvement	

[¥] Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

c. Proposed New PQRS Measures Available for Reporting for 2016 and Beyond and Proposed Changes to Existing PQRS Measures

Table 23 contains additional measures we propose to include in the PQRS measure set for CY 2016 and beyond. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted, as well as the MAP recommendations. Additional comments and measure information from the MAP review can be found at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

Please note that, in some cases specified below, we propose adding a measure to the PQRS measure set that the MAP believes requires further development prior to inclusion or does not support a measure for inclusion in the PQRS measure set. Please note that, while CMS takes these recommendations into consideration, in these instances, CMS believes the rationale provided for proposing the addition of a measure outweighs the MAP's recommendation.

TABLE 23: New Individual Quality Measures and those Included in Measures Groups for the PQRS to be Available for Satisfactory Reporting Beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who withdraw from hemodialysis peritoneal dialysis who are referred to hospice care.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports interdisciplinary communication between EPs providing palliative care to Medicare patients. This measure fills a clinical gap in the program, as it addresses palliative care.	Renal Physicians Association/ American Medical Association – Physician Consortium for Performance Improvement			X			
N/A/ N/A	N/A	Community/ Population Health	**Amblyopia Screening in Children:** The percentage of children who were screened for the presence of amblyopia at least once by their 6th birthday; and if necessary, were referred appropriately.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses screening for amblyopia within the pediatric population. This measure is also clinically robust, not duplicative of any measures in the PQRS, and	The Office of the National Coordinator for Health Information Technology / Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					reportable by EPs that provide care to pediatric patients.							
N/A/ N/A	N/A	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. This measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: - liver lesion < 0.5 cm - cystic kidney lesion < 1.0 cm - adrenal lesion < 1.0 cm	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports EPs within the profession of radiology. This process measure is clinically sound and addresses a clinical concept gap within radiology. This measure also addresses the important issue of assessing the overutilization of resources.	American College of Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT) or magnetic resonance imaging (MRI) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure targets imaging specialists and radiologists, who are currently underrepresented in the PQRS. This measure also fills a clinical gap in the PQRS, as it addresses preventing the overuse of imaging for incidental diagnoses.	American College of Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**Appropriate Treatment of MSSA - For MSSA Bacteremia, a β-lactam Antibiotic is the Drug of Choice in the Hospitalized Patient in the Absence of a Documented Allergy or Drug Intolerance:** Percentage of patients with MSSA bacteremia who received beta-lactam antibiotic (e.g., nafcillin or cefazolin) as definitive therapy.	2013 MAP stated there was "Insufficient Information" and provided no further comments.	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure represents a PQRS program gap and targets EPs who provide care within the inpatient care setting. This measure addresses a strong clinical need, as Beta-lactam use in patients with MSSA bacteremia is associated with improved outcomes for both hospital-acquired and community-acquired infections.	Infectious Diseases Society of America	X		X			
N/A/ N/A	N/A	Effective Clinical Care	**Chronic Opioid Therapy (COT) Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during COT documented in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is an analytically robust, and clinically-sound measure that identifies the importance of patient safety and evaluating patients on chronic opioid therapy. This	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					measure promotes patient safety within PQRS.							
N/A/ N/A	N/A	Effective Clinical Care	**Clinical Outcome Post-Endovascular Stroke Treatment:** Patients with 90 day mRs score of 0 to 2 post-endovascular stroke intervention.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses clinical outcomes for post-endovascular stroke treatment.	Society of Interventional Radiologists			X			
N/A/ N/A	N/A	Person and Caregiver-Centered Experience and Outcomes	**Clinical Response to Oral Systemic or Biologic Medications:** This measure evaluates the proportion of psoriasis patients receiving systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control, as measured by physician- and/or patient-reported outcomes, will increase patient satisfaction with and adherence to treatment.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcome measure represents an NQS domain gap, "Person and Caregiver Centered Experience and Outcomes," and targets a dermatology clinician group underrepresented in current PQRS measures.	American Academy of Dermatology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Community/ Population Health	**Cognitive Impairment Assessment Among At-Risk Older Adults:** Percentage of patients age 80 years or older at the start of the measurement period with documentation in the electronic health record at least once during the measurement period of (1) results from a standardized cognitive impairment assessment tool or (2) a patient or informant interview.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically sound, analytically feasible, and fills a clinical concept gap in PQRS for a high-risk elderly patients with cognitive impairment. This measure supports a variety of EPs that support this high-risk Medicare patient population.	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Communication and Care Coordination	**Coordinating Care - Emergency Department Referrals:** Percentage of patients (1) of any age with asthma or (2) ages 18 and over with chest pain who had a visit to the emergency department (not resulting in an inpatient admission), whose emergency department provider attempted to communicate with the patient's primary care provider or their specialist about the patient's visit to the emergency department.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports interdisciplinary communication between EPs providing palliative care to Medicare patients. This measure covers a gap in reporting for palliative care and promotes the clinical concept of interdisciplinary communication within the PQRS.	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
0711/ N/A	N/A	Communication and Care Coordination	**Depression Remission at Six Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment. The Patient Health Questionnaire (PHQ-9) tool is a widely accepted, standardized tool [Copyright © 2005 Pfizer, Inc. All rights reserved] that is completed by the patient, ideally at each visit, and utilized by the provider to monitor treatment progress. This measure additionally promotes ongoing contact between the patient and provider as patients who do not have a follow-up PHQ-9 score at six months (+/- 30 days) are also included in the denominator.	2013 MAP Report Recommendation was "Supports"	This is an outcomes measure that supports patients who struggle with the diagnosis of depression. This measure also supports EPs within the mental health profession.	Minnesota Community Measurement			X			
N/A/ N/A	N/A	Effective Clinical Care	**Documentation of a Health Care Proxy for Patients with Cognitive Impairment:** The percentage of patients with a diagnosis of dementia or a positive result on a standardized tool for assessment of cognitive impairment, with documentation of a designated health	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			care proxy during the measurement period.		partnership. This measure supports interdisciplinary communication between EPs providing cognitive impairment care to Medicare patients. This measure promotes the clinical concept of interdisciplinary communication within the PQRS as a whole.							
N/A/ N/A	N/A	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during COT documented in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses educating patients on opiate use. This measure is also clinically robust and not duplicative of any measures in the PQRS.	American Academy of Neurology			X			
N/A/ N/A	N/A	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Door to puncture time less than 2 hours for patients undergoing endovascular stroke treatment.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the	Society of Interventional Radiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					program, as it addresses the concept of capturing how much delay occurs in a facility for patients undergoing endovascular stroke treatment. This outcomes measure is clinically robust, clinically sound, and reportable by a variety of EPs who practice within the profession of endovascular stroke treatment.							
N/A/ N/A	N/A	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, SOAAP-R) or patient interview documented at least once during COT in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses the importance of patient safety and compliance. This measure is clinically robust and reportable by a variety of specialties.	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient Safety	**Extravasation of Contrast Following Contrast-Enhanced Computed Tomography (CT):** Percentage of final reports for patients aged 18 years and older who received intravenous iodinated contrast for a computed tomography (CT) examination who had an extravasation of contrast.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure evaluates contrast extravasation which is a patient safety issue not currently represented within the PQRS. This measure is applicable in both inpatient and outpatient settings and can be reported by radiologists, who currently have a limited number of measures to report within the PQRS.	American College of Radiology	X		X			
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Frequency of Inadequate Bowel Preparation:** Percentage of outpatient examinations with "inadequate" bowel preparation that require repeat colonoscopy in one year or less.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure determines inadequate bowel preparation and would compliment the existing colonoscopy measure within the PQRS program and is reportable by gastroenterologists.	American Society for Gastrointestinal Endoscopy	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**HIV Screening of STI patients:** Percentage of patients diagnosed with an acute STI who were tested for HIV.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fulfills an important clinical concept not represented in the PQRS. PQRS #205 "HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis" is related but not duplicative of this new measure. This measure is reportable by a variety of specialists, including primary care physicians, family practice doctors, OB-GYNs, urologists, and internal medicine physicians.	Centers for Disease Control and Prevention	X		X			
N/A/ N/A	N/A	Community/ Population Health	**HIV: Ever Screened for HIV:** Percentage of persons 15-65 ever screened for HIV.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically-sound and represents an	Centers for Disease Control and Prevention	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					important screening concept. This measure is reportable by a variety of specialists, including infectious disease physicians, OB-GYNs, internal medicine physicians, urologists, family practice doctors, and primary care providers.							
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Imaging in Adult Emergency Department (ED) Patients with Minor Head Injury:** Percent of adult patients who presented within 24 hours of a non-penetrating head injury with a Glasgow coma score (GCS)<=15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines prior to imaging.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses the appropriate use of imaging in the Emergency Department. Inappropriate use of imaging results in increased healthcare expenditures, unnecessary patient radiation exposure, and possible prolonged evaluation times. This measure is reportable by Emergency Department physicians.	American College of Emergency Physicians	X		X			
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Imaging in Pediatric ED Patients Aged 2 through 17 years with Minor Head Injury:** Percent of pediatric patients who presented within 24 hours of a non-penetrating head injury with a	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and	American College of Emergency Physicians	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Glasgow coma score (GCS) of 14 or 15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines (PECARN) prior to imaging.		practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically robust, analytically feasible, and fills a clinical gap in the program, as it addresses the importance of radiation safety within the adolescent population. This measure is also reportable by radiologists, emergency department physicians, neurologists, and pediatricians.							
N/A/ N/A	N/A	Patient Safety	**In-Hospital Mortality Following Elective Open Repair of AAAs:** Percentage of aymptomatic patients undergoing open repair of abdominal aortic aneurysms (AAA) who die while in hospital. This measure is proposed for both hospitals and individual providers.	Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcomes measure fills a clinical gap in the program, as it assesses mortality rate in AAA repair. This measure is clinically sound, analytically feasible, and is reportable by both general surgeons and vascular surgeons.	Society for Vascular Surgeons			X			
0053 /N/A	N/A	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a	2013 MAP Report Recommendation was "Supports"	CMS proposes adding NQF 0053: Osteoporosis Management in Women Who Had a Fracture as a new measure to replace	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.		the existing NQF 0048 (PQRS #40): Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older for CY 2016 PFS. NQF 0053 was harmonized with NQF 0048 which is being retired as a separate NQF endorsed measure. NQF 0053 represents a more harmonized and up-to-date measure than its predecessor.	Performance Improvement						
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Overuse Of Neuroimaging for Patients with Primary Headache And a Normal Neurological Examination:** Percentage of patients with a diagnosis of primary headache disorder whose health-related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the PQRS, as it addresses the overuse of neuroimaging, which further addresses both patient safety and efficient health care. This measure is reportable by neurologists and radiologists.	American Academy of Neurology	X		X			
N/A/ N/A	N/A	Effective Clinical Care	**Percentage of Patients Treated for Varicose Veins who are Treated with Saphenous Ablation and Receive an Outcomes Survey Before and after**	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because	Society of Interventional Radiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Treatment: Percentage of patients treated for varicose veins (CEAP C2) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that receive a disease specific patient reported outcome survey before and after treatment.		a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure provides a measurement tool of successful varicose vein therapy, and is reportable by general and vascular surgeons providing surgical treatment.							
N/A/ N/A	N/A	Effective Clinical Care	**Percentage of Patients with a Retrievable Inferior Vena Cava (IVC) Filter who are Appropriately Assessed for Continued Filtration or Device Removal:** Proportion of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it encourages patient safety and fosters patient follow-up for IVC filter removal. This measure is reportable by interventional radiologists who are currently underrepresented in the PQRS.	Society of Interventional Radiologists			X			
N/A/ N/A	N/A	Patient Safety	**Performing Cystoscopy at the time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of	Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			hysterectomy for pelvic organ prolapse.		NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses injury during hysterectomies. This measure is reportable by surgeons, OB-GYNs, urogynecologists, and urologists.							
N/A/ N/A	N/A	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent (aspirin or clopidogrel or equivalent such as aggrenox/tiglacor, etc.) within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the program, as it promotes secondary prevention of vascular disease beyond the timeframe of surgery. This measure is reportable by vascular surgeons, cardiovascular surgeons, and interventional radiologists.	Society for Vascular Surgeons	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports a gap in reporting for EPs that practice in anesthesia. This measure is an updated version of the current PQRS Measure #193: Perioperative Temperature, which is proposed for removal; however, this measure clinically supports positive outcomes for patients undergoing anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of landmarks of cecal intubation is performed to establish a complete examination.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as photodocumentation of cecal intubation allows a complete assessment of the cecum area that can aid in the prevention	American Society for Gastrointestinal Endoscopy	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					of colon cancer. Additionally, this measure would be applicable for gastroenterology specialists to report.							
N/A/ N/A	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post-Anesthesia Care Unit (PACU):** Percentage of patients who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure identifies a process of documentation that supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs that practice in anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	Effective Clinical Care	**Preoperative Assessment of Occult Stress Urinary Incontinence Prior to any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the program, as it addresses patients who do not receive preoperative assessment of occult stress urinary incontinence prior to pelvic organ prolapse repair. This measure is reportable by surgeons.	American Urogynecologic Society			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient Safety	**Preoperative Exclusion of Uterine Malignancy Prior to any Pelvic Organ Prolapse Repair:** Percentage of patients having documented assessment of abnormal uterine or postmenopausal bleeding prior to surgery for pelvic organ prolapse.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses patients who receive preoperative exclusion of uterine malignancy prior to any pelvic organ prolapse repair. This measure is reportable by gynecologists and urologists.	American Urogynecologic Society	X		X			
N/A/ N/A	N/A	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			
2152/ N/A	N/A	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol**	Encourage Continued Development	This measure will replace PQRS #173 "Preventive Care and	American Medical Association – Physician			X			X

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user.		Screening: Unhealthy Alcohol Use-Screening," as it represents a more clinically robust measure for unhealthy alcohol use. Additionally, this measure is broadly applicable to many specialties.	Consortium for Performance Improvement						
N/A/ N/A	N/A	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 1 month after surgery.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it address an outcome regarding injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.	American Urogynecologic Society	X		X			
N/A/ N/A	N/A	Patient Safety	**Proportion of Patients Sustaining a Major Viscus Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by perforation of a major viscus at the	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			time of index surgery that is recognized intraoperative or within 1 month after surgery.		submitted to the measures application partnership. This measure fills a clinical gap in the program, as it address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.							
N/A/ N/A	N/A	Patient Safety	**Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing a pelvic organ prolapse repair who sustain an injury to the ureter recognized either during or within 1 month after surgery.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**Quality of Life Assessment for Patients with Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcomes measure fills a clinical concept gap in the PQRS, as it addresses quality of life in patients with headaches.	American Academy of Neurology	X		X			
N/A/ N/A	N/A	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique	Not on this year's MUC list and thus not reviewed by MAP this year. Was on prior year MUC list and reviewed by MAP in prior year.	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure targets a provider group currently under represented in the program, radiologists. This measure also fills a current gap within the program for inpatient care.	American College of Radiology/ American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance	X		X			
N/A/ N/A	N/A	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** In patients assigned to endovascular treatment for obstructive arterial	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and	Society of Interventional Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.		practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in PQRS, as it addresses the concept of capturing unplanned complications (major amputation or surgical bypass), which are increasingly common for patients undergoing endovascular lower extremity revascularization. This measure is reportable by surgeons.							
N/A/ N/A	N/A	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of high-risk adult patients aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level ≥ 190 mg/dL; OR patients aged 40-75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level of 70-189 mg/dL who were prescribed or are	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure addresses statin therapy, which is an important treatment option for patients with cardiovascular disease, which includes up-to-date clinical guidelines. This measure is reportable by cardiologists and cardiology specialists, cardiovascular physicians, and primary care physicians.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/ Mathematica	X		X		X	X

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			already on statin medication therapy during the measurement period.									
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Unnecessary Screening Colonoscopy in Older Adults:** Percentage of patients age 86 or older who received an unnecessary screening colonoscopy.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses the overuse of colonoscopy which further addresses efficiency and cost aspects of health care.	American Gastroenterological Association			X			

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 24, we provide our proposals for a NQS domain change for measures that are currently available for reporting under the PQRS.

TABLE 24: Proposed NQS Domain Changes for Individual Quality Measures and those Included in Measures Groups for the PQRS beginning in 2016

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
0089/ 019	142v3	Effective Clinical Care (PFS 2015 final rule)	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69217). CMS is proposing to recategorize this measure from the effective clinical care domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
0420/ 131	N/A	Community/Population Health (PFS 2013 final rule)	Communication and Care Coordination	**Pain Assessment and Follow-up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims and registy in the PQRS in the CY 2013 PFS final rule. In the CY 2015 PFS final rule this measure was finalized for the addition of measures group reporting and finalized for designation as a cross-cutting measure (77 FR 69230). CMS is proposing to recategorize this measure from the community/population health domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
0643/ 243	N/A	Effective Clinical Care (PFS 2015 final rule)	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through registy in the PQRS in the CY 2013 PFS final rule (77 FR 69245). CMS is proposing to recategorize this measure from the effective clinical care domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
N/A/ 330	N/A	Effective Clinical Care (PFS 2015 final rule)	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
				for reporting through registryin the PQRS in the CY 2014 PFS final rule (78 FR 74638). CMS is proposing to recategorize this measure from the effective clinical care domain to the patient safety domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.
N/A/ 378	75v3	Effective Clinical Care (PFS 2015 final rule)	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through EHR in the PQRS in the CY 2014 PFS final rule (78 FR 74678). CMS is proposing to recategorize this measure from the effective clinical care domain to the community/ population health domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure is a measurement of process focused on the prevention of and screening for disease.

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 25, we propose to remove the following measures from reporting under the PQRS.

TABLE 25: Measures Proposed for Removal from the Existing PQRS Measure Set Beginning in 2016

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0241/ 033	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge. **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69219). CMS proposes removal in the CY 2016 PFS proposed rule as this measure is duplicated within the PQRS with current measure, Stroke and Stroke Rehabiliation: Discharged on Antithrombotic Therapy (PQRS#32).	American Academy of Neurology			X				
0048/ 040	Effective Clinical Care	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed. **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 final rule (77 FR 69220). CMS proposes removal in the CY 2016 PFS proposed rule as this measure (PQRS 40/NQF 0048) was combined within NQF 0053: Osteoporosis Management in Women Who Had a Fracture, to encompass	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		both the physician and health plan levels in one measure. NQF 0048: Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older is being retired and both measures will now be represented as one measure under the proposed new measure, Osteoporosis Management in Women Who Had a Fracture (NQF 0053).								
0323/ 081	Communication and Care Coordination	**Adult Kidney Disease: Hemodialysis Adequacy: Solute:** Percentage of calendar months within a 12 month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥ 90 days who have a spKt/V ≥ 1.2. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69224). CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS, and because EPs consistently meet performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	Renal Physicians Association			X				
0321/ 082	Effective Clinical Care	**Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69244).	Renal Physicians Association			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS, and because EPs consistently meet performance on this measure with performance rates close to 100%, suggesting there is no gap in care.								
N/A/ 172	Effective Clinical Care	**Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula:** Percentage of patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 3, 4 or 5) or End Stage Renal Disease (ESRD) requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69235). CMS proposes removal in the CY 2016 PFS proposed rule due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	Society for Vascular Surgeons	X		X				
AQA Endorsed /173	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use at least once within 24 months using a systematic screening method. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims, registry, EHR, and the Preventive Care Measures Group in the PQRS in the CY 2013 PFS final rule (77 FR 69235). In the CY 2014 PFS final rule, this measure was finalized for removal of claims and EHR	American Medical Association-Physician Consortium for Performance Improvement			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		reporting methods. CMS proposes removal of this measure in the CY 2016 PFS proposed rule and replacing it with NQF 2152: Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling. NQF 2152 includes counseling in addition to screening.								
N/A/ 193	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time. **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69238). CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS. Literature indicates that the adverse outcomes result in prolonged hospital stays and increased health care costs. CMS also recommends removal due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	American Society for Anesthesiologists	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0386/ 194	Effective Clinical Care	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period. **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims, registry, and measure groups in the PQRS in the CY 2013 PFS final rule (77 FR 69238). In the CY 2015 PFS final rule, this measure was finalized for a removal of claims and measures group reporting methods. CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS because documenting cancer stage is a basic standard of care for oncology. Cancer stage is standard of care that is documented early in the patient's care before treatment options are discussed.	American Medical Association-Physician Consortium for Performance Improvement/American Society of Clinical Oncology			X				
N/A/ 285	Effective Clinical Care	**Dementia: Screening for Depressive Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period. **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through the Dementia Measures Group in the PQRS in the CY 2013 PFS final rule (77 FR 69251). CMS proposes removal in the CY 2016 PFS proposed rule as this measure is duplicated within PQRS with current measure, Preventive Care and Screening: Screening for Clinical Depression and Follow-up (PQRS#134), which includes a	American Academy of Neurology Institute/American Psychological Association						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		follow-up concept.								
N/A/335	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.	American Medical Association-Physician Consortium for Performance Improvement			X				
N/A/336	Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.	American Medical Association-Physician Consortium for Performance Improvement			X				

NQF/ PQRS	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0076/349	Effective Clinical Care	**Optimal Vascular Composite:** Percent of patients aged 18 to 75 with ischemic vascular disease (IVD) who have optimally managed modifiable risk factors demonstrated by meeting all of the numerator targets of this patient level all-or-none composite measure: blood pressure less than 140/90, tobacco-free status, and daily aspirin use. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule (78 FR 74659). CMS proposes removal in the CY 2016 PFS proposed rule as parts of this composite measure are duplicative of Million Hearts measures.	Minnesota Community Measurement			X				

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 26, we propose to change the mechanism(s) by which an EP or group practice may report a respective PQRS measure beginning in 2016.

TABLE 26: Existing Individual Quality Measures and those Included in Measures Groups for the PQRS for Which Measure Reporting Updates will be Effective beginning in 2016

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0088/ 018	167v 3	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69216). In the CY 2015 PFS final rule (79 FR 67855), this measure was finalized for removal of claims and registry reporting methods. CMS proposes to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. Several level 1 RCT studies demonstrate the ability of timely treatment to reduce the rate and severity of vision loss from diabetes (Diabetic Retinopathy Study – DRS, Early Treatment Diabetic Retinopathy Study – ETDRS). Necessary examination prerequisites to applying the study results are that the presence and severity of both peripheral diabetic retinopathy and macular edema be accurately documented. In the RAND chronic disease quality project, while administrative data indicated that roughly half of the patients had an eye exam in the recommended time period, chart review data indicated that only 19% had documented evidence of a dilated examination. (McGlynn, 2003). Thus, ensuring timely treatment that could prevent 95% of the blindness due to diabetes requires the performance and documentation of key examination parameters. The documented level of severity of retinopathy and the documented presence or absence of macular edema assists with the on-going plan of care for the patient with diabetic retinopathy. This measure is the only measure in this proposed measures group that evaluates such documentation.	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance				X		X
0089/ 019	142v 3	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69217). CMS proposes to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. The physician that manages the ongoing care of the patient with diabetes should be aware of the patient's dilated eye examination and severity of retinopathy to manage the ongoing diabetes care. Such communication is important in assisting the physician to better manage the diabetes. Several studies have shown that better management of diabetes is directly related to lower rates of development of diabetic eye disease (Diabetes Control and Complications Trial – DCCT, UK Prospective Diabetes Study –	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance	X		X	X		X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		UKPDS).							
0236/ 044	N/A	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69220). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	Centers for Medicare & Medicare Services/Quality Insights of Pennsylvania			X			X
0062/ 119	134v 3	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims, registry, EHR, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69228). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	National Committee for Quality Assurance			X	X		X
0417/ 126	N/A	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69229). CMS proposes to replace PQRS 163 "Diabetes: Foot Exam" with PQRS 126 "Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation" in the Diabetes Measures Group in the CY 2016 PFS proposed rule. PQRS 126 targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.	American Podiatric Medical Association			X			X
0056/ 163	123v 3	**Diabetes: Foot Exam:** Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims, registry, EHR, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69233). CMS proposes to make this measure reportable via EHR only in the CY 2016 PFS proposed rule. CMS initially wanted to propose removal of this measure as it is a process measure that is low bar. However, to maintain alignment with the EHR Incentive	National Committee for Quality Assurance				X		

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description*	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		Program, under which this measure is also available for reporting in 2016, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.							
0130/ 165	N/A	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0131/ 166	N/A	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0114/ 167	N/A	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0115 /168	N/A	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0068/ 204	164v 3	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims, registry, EHR, GPRO, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69239). CMS proposes to add this measure to the proposed Cardiovascular Prevention measures group in the CY 2016 proposed rule, as the Cardiovascular Prevention measures group supports the Million Hearts initiative with overall cardiovascular health.	National Committee for Quality Assurance	X		X	X	X	X
0018/ 236	165v 3	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period **Rationale**: This measure has been reportable through PQRS for 5 years and was finalized for reporting through claims, registry, EHR, GPRO, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69243). In the CY 2015 PFS final rule (79 FR 67805), this measure was finalized for designation as a cross-cutting measure. CMS proposes to add this measure to the proposed Cardiovascular Prevention measures group in the CY 2016 proposed rule, as the Cardiovascular Prevention measures group supports the Million Hearts initiative with overall cardiovascular health.	National Committee for Quality Assurance	X		X	X	X	X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0022/ 238	156v 3	**Use of High-Risk Medications in the Elderly:** Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications. **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69244). In the CY 2015 PFS final rule (79 FR 67865), this measure was finalized for the addition of registry reporting method. CMS proposes to add this measure to the proposed Multiple Chronic Conditions Measures Group in the CY 2016 proposed rule, as the Multiple Chronic Conditions measures group offers broadly applicable measures which should be addressed in the management of patients with multiple chronic conditions.	National Committee for Quality Assurance			X	X		X
N/A/ 242	N/A	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69244). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Disease measures group allows CMS to evaluate patients diagnosed with Coronary Artery Disease.	American Medical Association – Physician Consortium for Performance Improvement /American College of Cardiology Foundation/American Heart Association						X
N/A/ 262	N/A	**Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69248). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	American Society of Breast Surgeons			X			
N/A/ 263	N/A	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method	American Society of Breast Surgeons			X			

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		Rationale: This measure has been reportable through PQRS for 4 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69248). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.							
N/A/ 337	N/A	**Tuberculosis Prevention for Psoriasis,Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier:** Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule (78 FR 74648). CMS proposes to add this measure to the Rheumatoid Arthritis Measures Group in the CY 2016 PFS proposed rule. This measure targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.	American Academy of Dermatology			X			X
0710/ 370	159v 3	**Depression Remission at Twelve Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through EHR in the PQRS in the CY 2014 PFS final rule (77 FR 69265). In the CY 2015 PFS final rule (79 FR 67867), this measure was finalized for reporting with the addition of the GPRO Web Interface reporting method. CMS proposes to adjust the reporting methods for this measure by adding registry for the CY 2016 proposed rule. CMS had intended to make this measure reportable via registry in the 2015 Program Year, however this was mistakenly never proposed on the 2015 NPRM.	Minnesota Community Measurement			X	X	X	

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

d. PQRS Measures Groups

Section 414.90(b) defines a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

We propose to add the following 3 new measures groups as shown in Tables 27, 28 and 29 that will be available for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provide the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these proposed measures groups that are proposed to be added, as indicated in Table 23 above, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated.

- Multiple Chronic Conditions Measures Group: We propose to add the Multiple Chronic Conditions Measures Group in the CY 2016 proposed rule. A large proportion of the Medicare population are impacted by Multiple Chronic Conditions, and providers that treat this population are often not recognized for the complexity of treatment for a patient with multiple chronic conditions. The addition of this measures group would specifically identify those providers that address the exponential complexity of treating the combination of these conditions rather than a sum of the individual conditions. This measures group addresses the

complexity of care that is required for patients that may have multiple disease processes that require clinical management and treatment.

• Cardiovascular Prevention Measures Group (Millions Hearts): We propose to add the Cardiovascular Prevention Measures Group in the CY 2016 proposed rule. Prior to 2015, the PQRS included a Cardiovascular Prevention Measures Group (Measures 2, 204, 226, 236, 241 and 317 in 2014 (78 FR 74741)). The measures group was removed for 2015 PQRS reporting due to clinical guideline changes that affected many of the measures. Given the efficacy of cardiovascular prevention on cardiovascular health, this measures group is being re-considered with an adjustment to align with current clinical guidelines. This measures group is also fully supported by the Million Hearts Initiative.

• Diabetic Retinopathy Measures Group: We propose to add the Diabetic Retinopathy Measures Group in the CY 2016 proposed rule. An increase in the frequency of Type 2 diabetes in the pediatric age group is associated with increased childhood obesity. The implications are significantly increased burdens of disability and complications associated with diabetes, including diabetic retinopathy, which has a projected prevalence of 6 million individuals with diabetic retinopathy by the year 2020 in the United States, and a prevalence rate of 28.5% in all adults with diabetes aged 40 and older. The addition of the Diabetic Retinopathy Measures Group would help to address this significant public health problem by allowing for the comprehensive evaluation of provider performance and patient outcomes related to a disease that threatens the eyesight of a very large population, and by supporting improvements in quality of care and outcomes related to diabetic retinopathy.

TABLE 27—CARDIOVASCULAR PREVENTION MEASURES GROUP FOR 2016 AND BEYOND

[Millions Hearts]

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	American Medical Association—Physician Consortium for Performance Improvement.
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and who had documentation of use of aspirin or another antithrombotic during the measurement period.	National Committee for Quality Assurance.
0018/236	Controlling High Blood Pressure: Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
N/A/317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
N/A/N/A	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of high-risk adult patients aged ≥21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level ≥190 mg/dL; OR patients aged 40–75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level of 70–189 mg/dL who were prescribed or are already on statin medication therapy during the measurement period. This is a new measure described in Table 23 above	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/ Mathematica.

TABLE 28—DIABETIC RETINOPATHY MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0059/001	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	National Committee for Quality Assurance.
0088/018	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance.

TABLE 28—DIABETIC RETINOPATHY MEASURES GROUP FOR 2016 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0089/019	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance.
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	National Committee for Quality Assurance.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	American Medical Association-Physician Consortium for Performance Improvement.
N/A/317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.

TABLE 29—MULTIPLE CHRONIC CONDITIONS MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-Physician Consortium for Performance Improvement.
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the current encounter. Normal Parameters: Age 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0420/131	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0101/154	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29—MULTIPLE CHRONIC CONDITIONS MEASURES GROUP FOR 2016 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0101/155	Falls: Plan of Care: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.
0022/238	Use of High-Risk Medications in the Elderly: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication b. Percentage of patients who were ordered at least two different high-risk medications.	National Committee for Quality Assurance.

We propose to amend the following previously finalized measures groups for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provide the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these proposed measures groups that are proposed to be added, as indicated in Table 23 above, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated.

TABLE 29A—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0134/043	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery who received an Internal Mammary Artery graft.	Society of Thoracic Surgeons.
0236/044	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0129/164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft (CABG) surgery who require postoperative intubation >24 hours.	Society of Thoracic Surgeons.
0130/165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons.
0131/166	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons.
0114/167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons.
0115/168	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons.

We propose to amend the following measures groups for reporting in the PQRS beginning in 2016.

TABLE 29B—DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND

[CMS proposes to add PQRS #134 preventive care and screening and delete PQRS #285 dementia: Screening for depressive symptoms from this measures group]

NQF/PQRS	Measure title and description	Measure developer
0326/047	Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29B—DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND—Continued

[CMS proposes to add PQRS #134 preventive care and screening and delete PQRS #285 dementia: Screening for depressive symptoms from this measures group]

NQF/PQRS	Measure title and description	Measure developer
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
N.A/280	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/281	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	American Medical Association-Physician Consortium for Performance Improvement.
N/A/282	Dementia: Functional Status Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/283	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/284	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/286	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/287	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/288	Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	American Academy of Neurology/American Psychological Association.

TABLE 29C—DIABETES MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add PQRS #126 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy and Delete PQRS #163 Diabetes: Foot Exam From This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0059/001	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.	National Committee for Quality Assurance.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-Physician Consortium for Performance Improvement.
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	National Committee for Quality Assurance.
0062/119	Diabetes: Medical Attention for Neuropathy: The percentage of patients 18–75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance.
0417/126	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy—Neurological Evaluation: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29D—PREVENTIVE CARE MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add NQF #2152 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling and Delete PQRS #173 Preventive Care and Screening: Unhealthy Alcohol Use—Screening From This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0046/039	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.
N/A/048	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.
0041/110	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	American Medical Association-Physician Consortium for Performance Improvement.
0043/111	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance.
2372/112	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.	National Committee for Quality Assurance.
0034/113	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance.
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter Normal Parameters: Age 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0418/134	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	American Medical Association-Physician Consortium for Performance Improvement.
2152/N/A	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user. This is a new measure described in Table 23 above.	American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29E—RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add PQRS 337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0054/108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD).	National Committee for Quality Assurance.
0421/128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous six months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous six months of the encounter Normal Parameters: Age 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0420/131	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
N/A/176	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology.
N/A/177	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.	American College of Rheumatology.

TABLE 29E—RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND—Continued

[CMS Proposes to Add PQRS 337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
N/A/178	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology.
N/A/179	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology.
N/A/180	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology.
N/A/337	Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier: Percentage of patients whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American College of Rheumatology.

e. Measures Available for Reporting in the GPRO Web Interface

We finalized the measures that are available for reporting in the GPRO web interface for 2015 and beyond in the CY 2015 PFS final rule (79 FR 67893 through 67902). The current measures available for reporting under the GPRO web interface are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_GPROWebInterface_MeasuresList_NarrativeSpecs_ReleaseNotes_12132013.zip.* We are proposing to adopt the following measure in Table 30 for reporting via the GPRO web interface beginning in 2016:

TABLE 30—MEASURE FOR ADDITION TO THE GROUP PRACTICE REPORTING OPTION WEB INTERFACE BEGINNING IN 2016 AND BEYOND

NQF/PQRS	GPRO Module	Measure and title description ¥	Measure steward	Other quality reporting programs
		Additions		
N/A/N/A	STAT–1 (Statin)	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of high-risk adult patients aged ≥21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level ≥190 mg/dL; OR patients aged 40–75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level of 70–189 mg/dL who were prescribed or are already on statin medication therapy during the measurement period. Rationale: Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This is a new measure that is proposed for the GPRO Web Interface in the PQRS for the CY 2016 PFS proposed rule. This measure addresses statin therapy, which is an important treatment option for patients with cardiovascular disease, which includes up-to-date clinical guidelines.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/Mathematica.	MSSP.

7. Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

The primary purpose of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) was to repeal the Medicare sustainable growth rate (SGR) and strengthen Medicare access by improving physician payments and making other improvements, as well as to reauthorize the Children's Health Insurance Program. In this section of the proposed rule, we are seeking public input on the following provisions of MACRA:

- Section 101(b): Consolidation of Certain Current Law Performance Programs with New Merit-based Incentive Payment System (hereinafter MIPS)
- Section 101(c): Merit-based Incentive Payment System
- Section 101(e): Promoting Alternative Payment Models

a. The Merit-Based Incentive Payment System (MIPS)

Section 1848(q) of the Act, added by section 101(c) of the MACRA, requires creation of the MIPS, applicable beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary shall: (1) Develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards for a performance period for a year; (2) using the methodology, provide for a composite performance score for each eligible professional for each performance period; and (3) use the composite performance score of the MIPS eligible professional for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the professional for the year. To aid in the planning and implementation of the MIPS, we are seeking public input on provisions related to the MIPS, including, but not limited to:

- *Low-volume threshold:* Section 1848(q)(1)(C)(iv) of the Act requires the Secretary to select a low-volume threshold to apply for purposes of excluding certain eligible professionals (as defined in section 1848(k)(3)(B) of the Act) from the definition of a MIPS eligible professional. The low-volume threshold may include one or more or a combination of the following: (1) The minimum number (as determined by the Secretary) of individuals enrolled under Medicare Part B who are treated by the eligible professional for the performance period involved; (2) the minimum number (as determined by the Secretary) of items and services furnished to individuals enrolled under Medicare Part B by such professional for such performance period; and (3) the minimum amount (as determined by the Secretary) of allowed charges billed by such professional under Medicare Part B for such performance period. We seek comment as to what would be an appropriate low-volume threshold for purposes of excluding certain eligible professionals (as defined in section 1848(k)(3)(B) of the Act) from the definition of a MIPS eligible professional. We also seek comment as to whether CMS should consider establishing a low-volume threshold using more than one or a combination of factors or, alternatively, whether CMS should focus on establishing a low-volume threshold based on one factor. We invite comments on which factors to include, individually or in combination, in determining a low-volume threshold.

Low-volume thresholds are currently used in other CMS reporting programs. For example, as required by section 1903(t)(2) of the Act, eligible professionals and acute care hospitals must meet certain Medicaid patient volume thresholds (in general, 30 percent for eligible professionals and 10 percent for acute care hospitals) to be eligble for the Medicaid EHR Incentive Program. We would consider proposing similar thresholds, such as to exclude eligible professionals that do not have at least 10 percent of their patient volume derived from Medicare Part B encounters from participating in the MIPs. We seek comment as to whether this would be an appropriate low-volume threshold for the MIPS. In addition, we invite comments on the applicability of existing low-volume thresholds used in other CMS reporting programs toward MIPs.

- *Clinical practice improvement activities:* Section 1848(q)(2)(A)(iii) of the Act provides for clinical practice improvement activities as one of the performance categories used in determining the composite performance score under the MIPS. In section 1848(q)(2)(C)(v)(III) of the Act, clinical practice improvement activities are defined as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act provides that the clinical practice improvement activities under subcategories specified by the Secretary for a performance period for a year must include at least the following subcategories:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

(5) Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an alternative payment model (as defined in section 1833(z)(3)(C) of the Act).

We seek comment on what activities could be classified as clinical practice improvement activities according to this definition.

b. Alternative Payment Models

Section 101(e) of MACRA, Promoting Alternative Payment Models, introduces a framework for promoting and developing alternative payment models (APMs) and providing incentive payments for eligible professionals who participate in APMs. The statutory amendments made by this section have payment implications for eligible professionals beginning in 2019. We are broadly seeking public comment on the topics in this section through this proposed rule.

In preparation to implement the changes introduced by section 101(e) of MACRA, we intend to publish questions for public comment on these amendments through a forthcoming Request for Information (RFI). Section 101(e) of MACRA includes the following provisions: Increasing Transparency of Physician-Focused Payment Models and Criteria and Process for Submission and Review of Physician-focused Payment Models (section 101(e)(1) of MACRA adds new section 1868(c) of the Act), Incentive Payments for Participation in Eligible Alternative Payment Models (section 101(e)(2) of MACRA adds new section 1833(z) of the Act), Encouraging

Development and Testing of Certain Models (section 101(e)(4) of MACRA amends section 1115A(b)(2) of the Act), a study on Integrating Medicare Alternative Payment Models in the Medicare Advantage payment system (section 101(e)(6) of MACRA), and Study and Report on Fraud Related to Alternative Payment Models under the Medicare Program (section 101(e)(7) of MACRA).

We intend to publish specific questions in the forthcoming RFI on topics within these provisions, including the following: The criteria for assessing physician-focused payment models; the criteria and process for the submission of physician-focused payment models eligible APMS, qualifying APM participants; the Medicare payment threshold option and the combination all-payer and Medicare payment threshold option for qualifying and partial-qualifying APM participants; the time period to use to calculate eligibility for qualifying and partial-qualifying APM participants, eligible APM entities, quality measures and EHR use requirements; and the definition of nominal financial risk for eligible APM entities. In anticipation of the future RFI and subsequent notice and comment rulemaking, we welcome comments on approaches to implementing any of the topics listed in this section, including in provisions not enumerated above, and any other related concerns.

J. Electronic Clinical Quality Measures (eCQM) and Certification Criteria; and Electronic Health Record (EHR) Incentive Program-Comprehensive Primary Care (CPC) Initiative and Medicare Meaningful Use Aligned Reporting

1. Background

The Health Information Technology for Economic and Clinical Health (HITECH) Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

Under section 1848(o)(2)(A)(iii) of the Act and the definition of ''meaningful EHR user'' under § 495.4, EPs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. For CY 2012 and subsequent years, § 495.8(a)(2)(ii) requires an EP to successfully report the CQMs selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable.

In the CY 2014 PFS final rule with comment period (78 FR 74756), we finalized our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. We stated that we believe it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions to correct minor inaccuracies found in prior measure versions. We stated that to ensure that CEHRT products can successfully transmit CQM data using the most recent version of the electronic specifications for the CQMs, it is important that the product be tested and certified to the most recent version of the electronic specifications for the CQMs.

2. Certification Requirements for Reporting Electronic Clinical Quality Measures (eCQMs) in the EHR Incentive Program and PQRS

In the CY 2015 PFS final rule with comment period (79 FR 67906), we finalized our proposal for the Medicare EHR Incentive Program that, beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs if they choose to report CQMs electronically for the Medicare EHR Incentive Program.

In the FY 2016 IPPS proposed rule (80 FR 24611 through 24615), HHS' Office of the National Coordinator for Health Information Technology (ONC) proposed a certification criterion for ''CQMs—report'' at 45 CFR 170.315(c)(3). This proposal would require that health information technology enable users to electronically create a data file for transmission of clinical quality measurement data in accordance with the Quality Reporting Document Architecture (QRDA) Category I (individual patient-level report) and Category III (aggregate report) standards, at a minimum. As part of the ''CQMs—report'' criterion, ONC also proposed to offer optional certification for EHRs according to the ''form and manner'' that CMS requires for electronic submission to participate in the EHR Incentive Programs and PQRS. These requirements are published annually as the ''CMS QRDA Implementation Guide'' and posted on CMS' Web site at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. The latest set of requirements (2015 CMS QRDA Implementation Guide for Eligible Professional Programs and Hospital Quality Reporting) combines the requirements for EPs, eligible hospitals, and CAHs. For a complete discussion of these proposals, we refer readers to 80 FR 24611 through 24615.

In the FY 2016 IPPS proposed rule (80 FR 24323 through 24629), we stated that we anticipate proposing to require EPs, eligible hospitals, and CAHs seeking to report CQMs electronically as part of meaningful use under the EHR Incentive Programs for 2016 to adhere to the additional standards and constraints on the QRDA standards for electronic reporting as described in the CMS QRDA Implementation Guide. We stated that we anticipate proposing to revise the definition of ''certified electronic health record technology'' at § 495.4 to require certification to the optional portion of the 2015 Edition CQM reporting criterion (proposed at 45 CFR 170.315(c)(3)) in the CY 2016 Medicare PFS proposed rule later this year.

Accordingly, to allow providers to upgrade to 2015 Edition CEHRT before 2018, we propose to revise the CEHRT definition for 2015 through 2017 to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept (CMS' ''form and manner'' requirements) if certifying to the 2015 Edition ''CQMs—report'' certification criterion at § 170.315(c)(3). Specifically, this would require technology to be certified to § 170.315(c)(3)(i) (the QRDA Category I and III standards) and § 170.315(c)(3)(ii) (the optional CMS ''form and manner''). We note that the proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on March 30, 2014 (80 FR 16732 through 16804) allows providers to use 2014 Edition or 2015 Edition certified EHR technology. These

proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We also propose to revise the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept. Specifically, this would require technology to be certified to § 170.315(c)(3)(i) (the QRDA Category I and III standards) and § 170.315(c)(3)(ii) (the optional CMS ''form and manner''). These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We are proposing these amendments at § 495.4 to ensure that providers participating in PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report CQMs according to the format that CMS requires for submission. We invite comment on our proposals.

3. Electronic Health Record (EHR) Incentive Program-Comprehensive Primary Care (CPC) Initiative Aligned Reporting

The Comprehensive Primary Care (CPC) initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, we pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, state, and other federal insurance plans are also offering enhanced support to primary care practices that provide high-quality primary care. There are approximately 480 CPC practice sites across seven health care markets in the U.S.

Under the CPC initiative, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (for a list of CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014, see 77 FR 54069 through 54075).

In the CY 2015 PFS final rule with comment period (79 FR 67906 through 67907), we finalized a group reporting option for CQMs for the Medicare EHR Incentive Program under which EPs who are part of a CPC practice site that successfully reports at least nine electronically specified CQMs across two domains for the relevant reporting period in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the requirements established for the Medicare EHR Incentive Program in the Stage 2 final rule. Additionally, only those EPs who are beyond their first year of demonstrating meaningful use may use this CPC group reporting option. The CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative. Therefore, whether CPC required electronic submission or attestation of CQMs, the CPC practice site must submit the CQM data in the form and manner required by the CPC Initiative.

We propose to retain the group reporting option for CPC practice sites as finalized in the CY 2015 PFS final rule, but for CY 2016, to require CPC practice sites to submit at least 9 CPC CQMs that cover 3 domains. In CY 2015, the CPC CQM subset was increased from a total of 11 to 13 measures, of which 8 measures fall in the clinical process/effectiveness domain, 3 in the population health domain, and 2 in the safety domain. Additionally, the CPC practice sites have had ample time to obtain measures from the CPC eCQM subset of meaningful use measures. Given the increased number of measures in the CPC eCQM set the addition of one measure to the safety domain, and the sufficient time that CPC practice sites have had to upgrade their EHR systems, it is reasonable to expect that CPC practice sites would have enough measures to report across the three domains as required for the Medicare EHR Incentive Program CQM reporting requirement. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the current requirements established for the Medicare EHR Incentive Program. As proposed in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Modifications to Meaningful Use in 2015 through 2017 proposed rule (80 FR 20375), EPs in any year of participation may electronically report clinical quality measures for a reporting period in 2016. Therefore, we are proposing that for CY 2016, EPs who are part of CPC practice site and are in their first year of demonstrating meaningful use may also use this CPC group reporting option to report their CQMs electronically instead of reporting CQMs by attestation through the EHR Incentive Program's Registration and Attestation System. However, we note that EPs who choose this CPC group reporting option must use a reporting period for CQMs of one full year (not 90 days), and that the data must be submitted during the submission period from January 1, 2017 through February 28, 2017. This means that EPs who elect to electronically report through the CPC practice site cannot successfully attest to meaningful use prior to October 1, 2016 (the deadline established for EPs who are first-time meaningful users in CY 2016) and therefore will receive reduced payments under the PFS in CY 2017 for failing to demonstrate meaningful use, if they have not applied and been approved for a significant hardship exception under the EHR Incentive Program. We invite public comment on these proposals.

K. Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

1. Background

As we discussed in the CY 2013 PFS final rule (77 FR 68978) and the CY 2014 PFS proposed rule (78 FR 43337), we are committed to supporting advanced primary care, including the recognition of care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth. In January 2015, the Secretary announced the vision of ''Better Care; Smarter Spending; Healthier People,'' with emphases on incentives (''promote value based payment systems; bring proven models to scale''); care delivery (''encourage the integration and coordination of clinical care services; improve population health; promote patient engagement through shared decision making''); and information (''create transparency on cost and quality information; bring electronic health information to the point of care for meaningful use''). More information on the Secretary's January 2015 announcement is available at *http://www.hhs.gov/news/press/2015pres/01/20150126a.html.* Accordingly, we are continuing to prioritize the development and implementation of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. These initiatives include the following payment policies, programs, and demonstrations:

- The Comprehensive Primary Care (CPC) initiative (described in this section of this proposed rule).

• Separate payment under the Medicare PFS beginning January 1, 2015, for new CPT code 99490. Under this CPT code, the fee-for-service program now pays separately for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions, as provided in the CY 2014 and 2015 PFS final rules with comment period (78 FR 74414–74427, and 79 FR 67715–67730 and 80 FR 14853, respectively).

• Medicare participation in multi-payer reform initiatives conducted by states in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration (described on CMS' Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *http://innovation.cms.gov/initiatives/Multi-Payer-Advanced-Primary-Care-Practice/*).

• The Medicare Shared Savings Program (described in the ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Final Rule'' that appeared in the November 2, 2011 **Federal Register** (76 FR 67802) and the subsequent final rule that addressed changes to the program, that appeared in the June 9, 2015 **Federal Register** (80 FR 32692).

• The testing of the Pioneer ACO Model, designed for experienced health care organizations (described on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/*).

• The testing of the ACO Investment Model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/ACO-Investment-Model/*).

The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. It is 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 Act 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. The CPC initiative began on October 1, 2012, and is scheduled to end on December 31, 2016. The initiative is being implemented in seven U.S. regions: statewide in Arkansas, Colorado, New Jersey, and Oregon; and regionally in Capital District-Hudson Valley, New York; Cincinnati-Dayton Region, Ohio/Kentucky; and Greater Tulsa, Oklahoma. There are approximately 480 participating practices spread across the regions, and 38 participating payers.

In the CPC initiative, we are collaborating with commercial payers and state Medicaid offices to test a payment model consisting of non-visit based per beneficiary per month care management payments and shared savings opportunities. Practices receive a monthly non-visit based care management fee for each Medicare FFS beneficiary and, in cases where the state Medicaid agency is participating, for each Medicaid FFS beneficiary. The monthly payment for each Medicare beneficiary averaged $20 per beneficiary per month during years 1 and 2 of the initiative (CY 2013–14), and averages $15 per beneficiary per month in years 3 and 4 (CY 2015 and CY 2016). The per beneficiary per month care management fee is in addition to the usual FFS payments that practitioners at the practice receive for furnishing services to their Medicare patients. Practices also receive non-visit based care management payments from other participating CPC payers and are expected to combine CPC revenues across payers to support a whole-practice care delivery transformation strategy. Additionally, we are offering each CPC practice the opportunity to share net savings generated from improved care to Medicare beneficiaries attributable to the practice. For each of three separate performance periods (that is, CY 2014, CY 2015, and CY 2016), we will calculate savings to the Medicare program generated by all CPC practices within each region, taken as a group. A portion of any savings accomplished at the level of each region will be distributed to practices in that region according to each practice's performance on quality metrics (patient experience measures, claims-based measures and electronic CQMs). Practices have similar shared savings opportunities with other CPC payers in their region.

The payment model is designed to support the provision by practices of the following five comprehensive primary care functions:

(1) *Risk Stratified Care Management:* The provision of intensive care management of appropriate intensity for high-risk, high-need, high-cost patients.

(2) *Access and Continuity:* 24/7 access to the care team; use of asynchronous communication; designation of a provider or care team for patients to build continuity of care.

(3) *Planned Care for Chronic Conditions and Preventive Care:* Proactive, appropriate care based on systematic assessment of patients' needs and personalized care plans.

(4) *Patient and Caregiver Engagement:* Active support of patients in managing their health care to meet their personal health goals; establishment of systems of care that include engagement of patients and caregivers in goal-setting and decision making, creating opportunities for patient and caregiver engagement throughout the care delivery process.

(5) *Coordination of Care across the Medical Neighborhood:* Management by the primary care practice of communication and information flow in support of referrals, transitions of care, and when care is received in other settings.

The CPC initiative is testing whether provision of these five comprehensive primary care functions by each practice site—supported by multi-payer payment reform, the continuous use of data to guide improvement, and meaningful use of health information technology—can achieve improved care, better health for populations, and lower costs, and can inform Medicare and Medicaid policy. Participating practices must demonstrate progress towards the provision of the five comprehensive primary care functions by meeting nine annual Milestones. These Milestones are: (1) Budget; (2) care management for high risk patients; (3) access and continuity; (4) patient experience; (5) quality improvement; (6) care coordination across the medical neighborhood; (7) shared decision making; (8) participate in learning collaborative; (9) health information technology. Full requirements of each Milestone are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*.

Practices must also report at least 9 of 13 specified electronic clinical quality measures (eCQMs) at the level of the practice site population as a method of measuring the quality of care delivered to all patients served by the practice, regardless of payer. We have aimed to align CPC clinical quality measures and reporting with other CMS programs to reduce burden on providers from having to report the same measures to multiple CMS programs through various reporting mechanisms. Under the CPC initiative, EPs participating in the CPC initiative who would otherwise need to report PQRS measures individually, or who are part of TINs that are participating as a whole in CPC, are able to satisfy their PQRS reporting requirements by successfully reporting data in accordance with the requirements for the CPC initiative. The decision to elect this waiver must be

made at the level of the CPC practice site (that is, all EPs at the site must elect the waiver). Additionally, completion of eCQM reporting in accordance with CPC requirements allows practices to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. This alignment between CPC and the Medicare EHR Incentive Program is described in section III.L. of this proposed rule.

We provide resources to help practices address the five comprehensive primary care functions through the CPC learning system, which includes regular webinars (regional and national), two in-person regional learning collaborative meetings per year, opportunities for moderated online collaboration with CPC practices across the country on specific issues, and access to providers of technical assistance (Regional Learning Faculty) in each region. Additionally, we support regular, professionally moderated collaborative meetings in each region between participating payers, practices and other interested parties (for example, hospital systems), to monitor the progress of the initiative at the regional level and ensure regional support to help participating practices succeed in the CPC initiative.

The first independent evaluation report of the CPC initiative was released on January 23, 2015, and covered impacts in the first four payment quarters of the initiative. The evaluator's report concluded that in these first four payment quarters, the initiative appears to have reduced total monthly Medicare Parts A and B expenditures per beneficiary (compared to what they would have been absent the CPC initiative) by $14, or 2 percent (not including care management fees paid). Results from this first year suggest that CPC has generated nearly enough savings in Medicare health care expenditures to offset care management fees paid by CMS. There were also statistically significant declines in hospitalizations and emergency department utilization. However, the report found that expenditure and service use impact estimates differed significantly across regions. No statistically significant impacts were seen in early measurements of quality. Further information about the CPC initiative, including the first independent evaluation report, is available on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/comprehensive-primary-care-initiative/*.

2. Interaction With the Chronic Care Management Code

The CPC initiative includes per beneficiary per month payments for care management services that closely overlap with the scope of service for the new chronic care management (CCM) services code under the PFS. To avoid duplicative payment for substantially the same services, practitioners participating in the CPC initiative may not bill Medicare for CCM services furnished to patients attributed to the practice for purposes of the practice's participation in the CPC initiative, as the payment for CCM services would be a duplicative payment for substantially the same services for which payment is made through the per beneficiary per month payment under CPC. Practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice for the purpose of the practice's participation as part of the CPC initiative.

3. Considerations for Potential Model 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): (1) The Secretary determines that the expansion is expected to either reduce Medicare 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 Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. We are not proposing to expand the CPC initiative at this time. The decision of whether or not to expand the CPC initiative will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act. The primary goal for this solicitation of public comments is to receive information about issues surrounding a potential expansion of the CPC initiative. Furthermore, consistent with our ongoing commitment to developing new models and refining existing models based on additional information and experience, CMS may modify existing models or test additional models under its testing authority under section 1115A of the Act. We may possibly do so, taking into consideration stakeholder input, including feedback received through public comments submitted in response to the discussion in this section.

The following list is not an exhaustive list of issues on which we are requesting public comments, and the inclusion of the list of issues is not, in any way, meant to imply that all of these issues would be addressed in any expanded model. The solicitation of public comments is for planning purposes, and we would use additional rulemaking if we decide to expand the initiative. We are soliciting input from the public on the following considerations for any potential expansion of the CPC initiative:

- *Practice readiness:* CPC practices currently are asked to reorganize their work flows to accomplish the five comprehensive primary care functions. Practices must use the most recent edition of Office of the National Coordinator Certified Electronic Health Records Technology (CEHRT), to perform and deliver comprehensive primary care and to monitor and report practice level electronic clinical quality measures (eCQMs) (full details of these requirements are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*). We are interested in understanding the proportion of primary care practices ready for these transformation expectations and whether readiness varies systematically for differently structured practices (for example, small primary care practices, multi-specialty practices, and employed primary care practices within integrated health systems).
- *Practice standards and reporting:* We seek input on the value and operational burden of the current CPC Milestones approach, including the current system of quarterly reporting via a web portal (full details of these requirements are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*).
- *Practice groupings:* We seek input as to whether any potential expansion should be limited to existing CPC regions, or include new geographic regions. We are also interested in whether multi-site group practices would be willing to involve all their primary care sites in a potential expansion of the CPC initiative (practice sites currently participating in the CPC initiative were selected for the model individually), and how practices could

best be grouped for the purposes of calculating shared savings.

• *Interaction with state primary care transformation initiatives:* Though many primary care transformation efforts predated the start of the CPC initiative, the number of such efforts has grown significantly during the existence of this initiative. Various states are leading their own efforts to transform primary care practices. Although these efforts may have processes and goals that are similar to those in the CPC initiative, requirements and outcomes can differ in important ways. We are interested in whether a potential expansion of the CPC initiative could and should exist in parallel in a state with a separate state-led primary care transformation effort, especially if Medicare is participating in that effort.

• *Learning activities:* The CPC initiative currently offers a range of live, telephone, and online support through national and regional ''learning communities.'' In the first 2 years of the model these efforts have been focused on building practices' capability to deliver comprehensive primary care through fulfilment of the CPC Milestones. In the remaining period of the model, these learning activities are aimed at adapting and optimizing clinical services within the five CPC comprehensive primary care functions to achieve the aims of the CPC initiative. We are interested in what support practices would require to provide the five comprehensive primary care CPC functions in a potential expansion of the CPC initiative, and the readiness of the private sector to respond to the need for this support. We are also interested in the willingness and ability of existing state and regional primary care or patient centered medical home learning collaboratives to support practices in an a potential expansion of the CPC initiative.

• *Payer and self-insured employer readiness:* We seek input on the readiness of currently participating payers in the CPC initiative to expand their current investment in CPC; and the readiness of new payers, including self-insured employers, to enter the initiative under a potential expansion. We are interested in thresholds for payer participation, for example, whether there should be a minimum threshold of payer participation for a region, or at the level of an individual practice, in order for a payer to be eligible for participation in a potential expansion of the CPC initiative. We also seek input about the best methods for payers to engage with one another, participating practices, and CMS under a potential expansion.

• *Medicaid:* The CPC initiative is a multi-payer initiative that seeks to include as many payers as possible to provide practices with sufficient resources for a practice-level transformation that benefits their entire patient population. A number of state Medicaid agencies currently participate as payers in the CPC initiative for their fee-for-service enrollees. We are interested in whether state Medicaid agencies would be willing to participate in a potential expanded CPC initiative for their fee-for-service enrollees. We are also interested in whether Medicaid managed care plans would be willing to participate in a potential expanded CPC initiative.

• *Quality reporting:* We are interested in comment on practice readiness to report eCQMs, and payer interest in using practice site level data rather than their own enrollees' information for performance based payments, including shared savings, in a potential expansion of the CPC initiative.

• *Interaction with the CCM fee:* The CY 2015 PFS final rule with comment period (79 FR 67729) discussed the policy for the billing of CCM services when a practitioner is participating in the CPC initiative, as described earlier in this proposed rule. We seek input on how payment for CCM services might interact with a potential expansion of the CPC initiative and affect practice interest in participation.

• *Provision of data feedback to practices:* We currently send quarterly feedback reports to practices including cost and utilization information for the Medicare FFS attributed population of that practice. We seek comment about how we can best provide actionable data to support quality improvement and promote attention to total cost of care under a potential expansion.

L. 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)).

We identified the following policies under the Shared Savings Program that we are addressing in this proposed rule.

1. Quality Measures and Performance Standard

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 establishing the Shared Savings Program and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; and 79 FR 67907 through 67931), we established the quality performance standards that ACOs must meet to be eligible to share in savings that are generated. 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 that will apply for 2 years. Through these previous rulemakings, we worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS. Currently, eligible professionals participating in an ACO may qualify for the PQRS incentive payment under the

Shared Savings Program or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the GPRO web interface.

We identified a few policies related to the quality measures and quality performance standard that we are proposing in this rule. Specifically, we are proposing to add a new quality measure to be reported through the CMS web interface and to adopt a policy for addressing quality measures that no longer align with updated clinical guidelines or where the application of the measure may result in patient harm.

a. Existing Quality Measures and Performance Standard

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 Shared Savings Program 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 the CY 2015 PFS final rule with comment period, we made a number of updates to the quality performance standard, including adding new measures that ACOs must report, retiring measures that no longer aligned with updated clinical guidelines, reducing the sample size for measures reported through the CMS web interface, establishing a schedule for the phase in of new quality measures, and establishing an additional reward for quality improvement. In the CY 2015 PFS final rule with comment period, we finalized an updated measure set of 33 measures.

Quality measures are submitted by the ACO through the GPRO 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 GPRO web interface are also used to determine whether eligible professionals participating in an ACO avoid the PQRS and automatic Value Modifier payment adjustments for 2015 and subsequent years. Eligible professionals in an ACO may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the GPRO web interface. Beginning with the 2017 Value Modifier, performance on the ACO GPRO web interface measures and all cause readmission measure will be used in calculating the quality component of the Value Modifier for eligible professionals 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 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, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment.

In selecting the 33 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 selecting the set of 33 measures finalized in the CY 2015 PFS final rule with comment period, we sought to include both process and outcome measures, including patient experience of care (79 FR 67907 through 67931). 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. We noted, however, that as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, 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.

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. We are 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. 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.

b. Proposed New Measure To Be Used in Establishing Quality Standards That ACOs Must Meet To Be Eligible for Shared Savings

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the GPRO web interface reporting for PQRS. Based on these reviews, in the CY 2015 PFS final rule with comment period, we retired several measures that no longer aligned with updated clinical guidelines regarding cholesterol targets. As a result of retiring measures that did not align with updated clinical practice, we identified a gap in the Shared Savings Program measure set for measures that address treatment for patients at high risk of cardiovascular disease due to high cholesterol. Cardiovascular disease affects a high volume of Medicare beneficiaries and the prevention of cardiovascular disease as well as its treatment is important. Following further analysis and coordination with agencies such as the Centers for Disease Control and Prevention and the Agency for Healthcare Research & Quality, we are proposing to add a new statin therapy measure for the Shared Savings

Program that has been developed to align with the updated clinical guidelines and PQRS reporting. We are proposing to add one new measure to the Preventive Health domain, which would increase our current total number of measures from 33 to 34 measures. Data collection for the new measure would occur through the CMS web interface. Table 31 lists the Shared Savings Program quality measure set, including the one measure we are proposing to add, that would be used to assess ACO quality starting in 2016.

- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

We propose to add the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease to the Preventive Health domain. The measure was developed by CMS in collaboration with other federal agencies and the Million Hearts® Initiative and is intended to support the prevention and treatment of cardiovascular disease by measuring the use of statin therapies according to the updated clinical guidelines for patients with high cholesterol. The measure reports the percentage of beneficiaries who were prescribed or were already on statin medication therapy during the measurement year and who fall into any of the following three categories:

1. High-risk adult patients aged greater than or equal to 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD);

2. Adult patients aged greater than or equal to 21 years with any fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level that is greater than or equal to 190 mg/dL; or

3. Patients aged 40 to 75 years with a diagnosis of diabetes with a fasting or direct LDL–C level of 70 to 189 mg/dL who were prescribed or were already on statin medication therapy during the measurement year.

The measure contains multiple denominators to align with the updated clinical guidelines for cholesterol targets and would replace the low-density lipid control measures previously retired from the measure set. We are proposing this measure to continue Shared Savings Program alignment with the PQRS program (Table 30) and Million Hearts Initiative. We propose that the multiple denominators will be equally weighted when calculating the performance rate. The measure was reviewed by the NQF Measure Applications Partnership (MAP) and the MAP encouraged further development (Measures Under Consideration (MUC) ID: X3729).

As a result, we are seeking public comment on the implementation of the measure for the Shared Savings Program. We are seeking comment on whether the measure should be considered a single measure with weighted denominators or three measures given the multiple denominators were developed to adhere to the updated clinical guidelines. In addition, the use of multiple denominators raises questions on how the measure should be benchmarked for the Shared Savings Program. Therefore, we are seeking public feedback on the benchmarking approach for the measure, such as whether the measure should be benchmarked as a single measure or three measures. The measure specifications that were submitted to the NQF MAP include multiple denominators, which may require larger sample sizes to accommodate exclusions when identifying relevant beneficiaries for each of the denominators used for CMS web interface reporting. Due to the multiple denominators, there may be a large number of beneficiaries who may not meet each denominator for reporting and would result in a low number of beneficiaries meeting the measure denominators. Hence, we are proposing to increase the size of the oversample for this measure from the normal 616 beneficiaries for CMS web interface reporting to an oversample of 750 or more beneficiaries. We are proposing such an oversample size for this measure to account for reporting on the multiple denominators and to ensure a sufficient number of beneficiaries meet the measure denominators for reporting. The consecutive reporting requirement for measures reported through the CMS web interface would remain at 248 beneficiaries. We are proposing that the measure will be pay for reporting for 2 years and then phase into pay for performance in the third year of the agreement period, as seen in Table 31. Previously, we finalized that new measures will have a 2-year transition period before being phased in as pay for performance (79 FR 67910). However, we are also seeking comment on whether stakeholders believe the measure should be pay for reporting for the entire agreement period due to the application of multiple denominators for a single measure. In summary, we seek comment on our proposal to include this measure in the Preventive Health domain, whether it should be treated as a single or multiple measures for reporting and benchmarking, the transition of the measure into pay for performance or if they measure should remain pay for reporting for the entire agreement period, and the size of the oversample to ensure sufficient identification of beneficiaries for reporting.

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO Measure No.	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.		NQF #0005, AHRQ.	Survey	R	P	P
	ACO–2	CAHPS: How Well Your Doctors Communicate.		NQF #0005, AHRQ.	Survey	R	P	P
	ACO–3	CAHPS: Patients' Rating of Doctor.		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

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
	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/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).	.....	NQF #TBD, 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
	ACO–9	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5).	.....	Adapted NQF #0275, AHRQ.	Claims	R	P	P
	ACO–10	Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8).	.....	Adapted NQF #0277, AHRQ.	Claims	R	P	P
	ACO–11	Percent of PCPs who Successfully Meet Meaningful Use Requirements.	.....	NQF #N/A, CMS.	EHR Incentive Program Reporting.	R	P	P
	ACO–39	Documentation of Current Medications in the Medical Record.	.....	NQF #0419, CMS.	CMS Web Interface.	R	P	P
	ACO–13	Falls: Screening for Future Fall Risk.	.....	NQF #0101, NCQA.	CMS Web Interface.	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 #NA, NCQA.	CMS Web Interface.	R	R	P
	ACO–21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.	.....	CMS	CMS Web Interface.	R	R	P
	ACO–42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	X	NQF #TBD, MUC ID: X3729, CMS.	CMS Web Interface.	R	R	P

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
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
Clinical Care for At Risk Population —Heart Failure.	ACO–31	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	.....	NQF #0083, AMA–PCPI.	CMS Web Interface.	R	R	P
Clinical Care for At Risk Population—Coronary Artery Disease.	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%).	.....	NQF # 0066, ACC.	CMS Web Interface.	R	R	P

The quality scoring methodology is explained in the regulations at § 425.502 and in the preamble to the November 2011 final rule with comment period (76 FR 67895 through 67900). As a result of this proposed addition, each of the four domains will include the following number of quality measures (See Table 32 for details.):

- Patient/Caregiver Experience of Care—8 measures
- Care Coordination/Patient Safety—10 measures
- Preventive Health—9 measures
- At Risk Population—7 measures (including 6 individual measures and a 2-component diabetes composite measure)

Table 32 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes with the proposed additional measure in the At-Risk Population domain. The total possible points for the Preventive Health domain would increase from 16 points to 18 points. Otherwise, the current methodology for calculating an ACO's overall quality performance score would continue to apply. We are also seeking comment on whether the proposed Statin Therapy measure, with multiple denominators, should be scored at more than 2 points if commenters believe this measure should be treated as multiple measures within the Preventive Health domain instead of a single measure. For instance, the measure could be scored as 3 points, 1 point for each of the three denominators, due to the clinical importance of prevention and treatment of cardiovascular disease and the complexity of the measure. The EHR measure is currently the only measure scored more than 2 points in the current measure set, but given the multiple denominators that exist within the Statin Therapy measure, it could be scored greater than 2 points as well.

TABLE 32—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 (%)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	10 measures. Note that the EHR measure is double-weighted (4 points).	22	25
Preventive Health	9	9 measures	18	25

TABLE 32—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 (%)
At-Risk Population	7	6 individual measures, plus a 2-component diabetes composite measure, scored as one.	12	25
Total in all Domains	34	33	68	100

We believe that the proposed addition of the Statin Therapy quality measure to the quality measure set for the Shared Savings Program would further enhance the quality of care patients receive from ACO participants and ACO providers/suppliers, better reflect clinical practice guidelines and high quality care, enhance alignment with PQRS and the Million Hearts ® Initiative, and focus on important preventive care and effective treatments for high prevalence conditions.

c. Proposed Policy for Measures No Longer Aligning With Clinical Guidelines, High Quality Care or Outdated Measure May Cause Patient Harm

We have encountered circumstances where changes in clinical guidelines result in quality measures within the Shared Savings Program quality measure set no longer aligning with best clinical practice. For instance, in the CY 2015 PFS final rule with comment period we retired measures that were no longer consistent with updated clinical guidelines for cholesterol targets, but we were unable to finalize retirement of the measures for the 2014 reporting year due to the timing of the guideline updates and rulemaking cycle. We issued an update in the 2014 Shared Savings Program benchmark guidance document that maintained these measures as pay-for-reporting for the 2014 reporting year due to the measures not aligning with updated clinical evidence.

However, given the frequency of changes that occur in scientific evidence and clinical practice, we are proposing to adopt a general policy under which we will maintain measures as pay-for-reporting, or revert pay-for-performance measures to pay-for-reporting measures, if the measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or when clinical evidence suggests that continued measure compliance and collection of the data may result in harm to patients. This flexibility will enable us to respond more quickly to clinical guideline updates that affect measures without waiting until a future rulemaking cycle to retire a measure or revert to pay for reporting. We expect that we will continue to retire measures through the annual PFS final rule with comment period as clinical guidelines change; however, the timing of clinical guideline updates may not always correspond with the rulemaking cycle. Under this proposal, if a guideline update is published during a reporting year and the measure owner determines the measure specifications do not align with the updated clinical practice, we would have the authority to maintain a measure as pay for reporting or revert a pay-for-performance measure to pay for reporting and finalize changes in the subsequent PFS final rule with comment period. Therefore, we are proposing to add a new provision at § 425.502(a)(5) to reserve the right to maintain a measure as pay for reporting, or revert a pay-for-performance measure to pay for reporting, if a measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or clinical evidence suggests that continued application of the measure may result in harm to patients. The measure owner will inform CMS if a measure's specification does not align with updated guidelines or if continued application of the measure may result in patient harm. We would then implement any necessary change to the measure in the next PFS rulemaking cycle by either retiring the measure or maintaining it as pay for reporting. We seek comment on this proposal and whether there may be additional criteria we should consider in deciding when it may be appropriate to maintain a measure as pay-for-reporting or revert from pay-for-performance back to pay-for-reporting.

d. Request for Comment Related to Use of Health Information Technology

In the November 2011 final rule, we included a measure related to the use of health information technology under the Care Coordination/Patient Safety domain: the percent of PCPs within an ACO who successfully qualify for an EHR Incentive Program incentive (76 FR 67878). In finalizing this measure, we included eligible professionals that qualified for payments to adopt, implement, or upgrade EHR technology, in addition to those receiving a payment for meeting Meaningful use Requirements. We selected this measure as opposed to other proposed measures in order to focus on EHR adoption among the primary care physicians within an ACO. Finally, we chose to focus on this measure because it represented a structural measure of EHR program participation that is not duplicative of measures within the EHR Incentive program for which providers may already qualify for incentive payments or face penalties. Although this was the only measure we finalized related to use of health information technology, we chose to double weight this measure for scoring purposes in order to signal the importance of health information technology for ACOs (76 FR 67895).

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change the name and specification of this measure to ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' in order to reflect the transition from incentive payments to downward payment adjustments in 2015 (79 FR 67912). We believe this name will more accurately depict successful use and adoption of EHR technology.

We continue to believe that measures which encourage the effective adoption and use of health information technology among participants in accountable care initiatives are an important way to signal the importance of technology infrastructure in supporting successful ACOs, especially as they mature and assume additional risk. Since the initial EHR quality measure was finalized in 2011, the EHR Incentive Program and Meaningful Use requirements have shifted from an initial focus on technology adoption and data capture to interoperable exchange of data across systems and the use of more advanced health IT functions to support care coordination and quality

improvement. A notice of proposed rulemaking for ''Stage 3'' of the EHR Incentive program, was released in March 2015 (80 FR 16731), along with a related proposed 2015 Edition of ONC certification criteria (80 FR 16804), which aim to support providers' ability to exchange a common clinical dataset across the continuum of care. In addition, ONC has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*) which focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017.

We believe that the widespread inclusion of these capabilities within health IT systems, and their adoption and effective use by providers, will greatly enhance ACOs' ability to coordinate care for beneficiaries with practitioners both within and outside their ACO and more effectively manage the total cost of care for attributed patients. While we are not proposing any changes to the current measure ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' (ACO–11) at this time, we are seeking comment on how this measure might evolve in the future to ensure we are incentivizing and rewarding providers for continuing to adopt and use more advanced health IT functionality as described above, and broadening the set of providers across the care continuum that have adopted these tools. We welcome comments on the following questions:

- Although the current measure focuses only on primary care physicians, should this measure be expanded in the future to include all eligible professionals, including specialists?
- How could the current measure be updated to reward providers who have achieved higher levels of health IT adoption?
- Should we substitute or add another measure that would focus specifically on the use of health information technology, rather than meeting overall Meaningful Use requirements, for instance, the transitions of care measure required for the EHR Incentives Program?
- What other measures of IT-enabled processes would be most relevant to participants within ACOs? How could we seek to minimize the administrative burden on providers in collecting these measures?

e. Conforming Changes To Align With PQRS

Under the Shared Savings Program rules at § 425.504, ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit quality measures using a CMS web interface (currently the CMS Group Practice Reporting Option Web Interface) to satisfactorily report on behalf of their eligible professionals for purposes of the PQRS payment adjustment under the Shared Savings Program. Under § 425.118(a)(4), all Medicare enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program, including the quality reporting requirements. Thus, each eligible professional that bills under the TIN of an ACO participant must be included on the ACO provider/supplier list in accordance with the requirements in § 425.118.

The methodology for applying the PQRS adjustment to group practices takes into account the services billed by all eligible professionals through the TIN of the group practice, however, the references to ''ACO providers/suppliers who are eligible professionals'' in § 425.504 indicate that the ACO provider/supplier list should be used to determine the eligible professionals. Our intent and current practice is to treat the ACO and its ACO participants the same as any other physician group electing to report for purposes of PQRS through the GPRO Web Interface. We therefore have determined that it is necessary to modify the language in § 425.504 for clarity and to bring it into alignment with the methodology used to determine the applicability of the payment adjustment under the PQRS GPRO methodology so that it is consistently applied to eligible professionals billing through an ACO participant TIN. We propose to revise § 425.504(a) to replace the phrase ''ACO providers/suppliers who are eligible professionals'' and ''ACO providers/suppliers that are eligible professionals'' with the phrase ''eligible professionals who bill under the TIN of an ACO participant'' along with conforming changes anywhere the term ACO providers/suppliers appears in § 425.504. We believe these changes are necessary to clarify that the requirement that the ACO report on behalf of these eligible professionals applies in a way that is consistent with the PQRS GPRO policies and also addresses mid-year updates to and deletions from the ACO provider/supplier list. For example, this change clarifies that an ACO must still report quality data for services billed under the TIN of an ACO participant by an eligible professional that was an ACO provider/supplier for a portion of the performance year, but was removed from the ACO provider/supplier list mid-year when he or she started a new job and ceased billing under the TIN of the ACO participant.

2. Assignment of Beneficiaries to ACOs

Section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in paragraph (h)(1)(A).'' As we have explained in detail elsewhere (79 FR 72792), we established the current list of codes that constitute primary care services under the Shared Savings Program at § 425.20 because we believed the listed codes represented a reasonable approximation of the kinds of services that are described by the statutory language which refers to assignment of ''Medicare fee for service beneficiaries to an ACO based on their utilization of primary care services'' furnished by physicians. We propose the following revisions to the assignment of beneficiaries to ACOs under the Shared Savings Program.

a. Assignment of Beneficiaries Based on Certain Evaluation and Management Services in SNFs

As discussed in detail in the November 2014 proposed rule for the Shared Savings Program (79 FR 72792 through 72793), we welcomed comment from stakeholders on the implications of retaining certain evaluation and management codes used for physician services furnished in SNFs and other nursing facility settings (CPT codes 99304 through 99318) in the definition of primary care services. As we noted in the proposed rule, in some cases, hospitalists that perform evaluation and management services in SNFs have requested that these codes be excluded from the definition of primary care services so that their ACO participant TIN need not be exclusive to only one ACO based on the exclusivity policy established in the November 2011 final rule (76 FR 67810 through 67811). The requirement under § 425.306(b) that an ACO participant TIN be exclusive to a single ACO applies when the ACO

participant TIN submits claims for primary care services that are considered in the assignment process. However, ACO participant TINs upon which beneficiary assignment is not dependent (that is, ACO participant TINs that do not submit claims for primary care services that are considered in the assignment process) are not required to be exclusive to a single ACO.

In response to the discussion in the Shared Savings Program proposed rule of our policy of including the codes for SNF visits, CPT codes 99304 through 99318, in the definition of primary care services, some commenters objected to inclusion of SNF visit codes, believing a SNF is more of an extension of the inpatient setting rather than a component of the community based primary care setting. As a result, these commenters believe that ACOs are often inappropriately assigned patients who have had long SNF stays but would not otherwise be aligned to the ACO and with whom the ACO has no clinical contact after their SNF stay. Some commenters draw a distinction between such services provided in two different places of service, POS 31 (SNF) and POS 32 (NF). Although the same CPT visit codes are used to describe these services in SNFs (POS 31) and NFs (POS 32), the patient population is arguably quite different. These commenters suggest excluding SNF visit codes furnished in POS 31 to potentially relieve hospitalists from the requirement that these ACO professionals must be exclusive to a single ACO if their services are considered in assignment. Patients in SNFs (POS 31) are shorter stay patients who are receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back in the community. Patients in a SNF (POS 31) require more frequent practitioner visits—often from 1 to 3 times a week. In contrast, patients in NFs (POS 32) are almost always permanent residents and generally receive their primary care services in the facility for the duration of their life. Patients in the NF (POS 32) are usually seen every 30 to 60 days unless medical necessity dictates otherwise.

We agree that it would be feasible to use POS 31 to identify claims for services furnished in a SNF. Therefore, we are proposing to amend our definition of primary care services at § 425.20, for purposes of the Shared Savings Program, to exclude services billed under CPT codes 99304 through 99318 when the claim includes the POS 31 modifier. We recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back in the community to the primary care professionals who are typically responsible for providing care to meet their true primary needs. If we finalize this proposal, we anticipate applying this revised definition of primary care services for purposes of determining ACO eligibility during the application cycle for the 2017 performance year, which occurs during 2016, and the revision would be then be applicable for all ACOs starting with the 2017 performance year. This would align the assignment algorithms for both new ACOs entering the program and existing ACOs ensuring that beneficiaries are being assigned to the most appropriate ACO and that assigned beneficiary populations are determined using consistent assignment algorithms for all ACOs, as well as aligning our program operations with the application cycle. We propose to make a conforming change to the definition of primary care services in paragraph (2) by indicating that the current definition will be in use for the 2016 performance year and to add a new definition of primary care services in paragraph (4), which excludes SNFs from the definition of primary care services effective starting with the 2017 performance year. We believe that excluding services furnished in SNFs from the definition of primary care services will complement our goal to assign beneficiaries to an ACO based on their utilization of primary care services. Further, based on preliminary analysis, we do not expect removal of these claims from the assignment process would result in a significant reduction in the number of beneficiaries assigned to ACOs, although we recognize that assignment to some ACOs may be more affected than others, depending on the practice patterns of their ACO professionals. We invite comments on these issues.

b. Assignment of Beneficiaries to ACOs That Include ETA Hospitals

We have developed special operational instructions and processes (79 FR 72801 through 72802) that enable us to include primary care services performed by physicians at ETA hospitals in the assignment of beneficiaries to ACOs under § 425.402. ETA hospitals are hospitals that, under section 1861(b)(7) of the Act and § 415.160, have voluntarily elected to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in lieu of Medicare PFS payments that might otherwise be made for these services. We use institutional claims submitted by ETA hospitals in the assignment process under the Shared Savings Program because ETA hospitals are paid for physician professional services on a reasonable cost basis through their cost reports and no other claim is submitted for such services. However, ETA hospitals bill us for their separate facility services when physicians and other practitioners provide services in the ETA hospital and the institutional claims submitted by ETA hospitals include the HCPCS code for the services provided. To determine the rendering physician for ETA institutional claims, we use the NPI listed in the ''other provider'' NPI field on the institutional claim. Then we use PECOS to obtain the CMS specialty for the NPI listed on the ETA institutional claim.

These institutional claims do not include allowed charges, which are necessary to determine where a beneficiary received the plurality of primary care services as part of the assignment process. Accordingly, we use the amount that would otherwise be payable under the PFS for the applicable HCPCS code, in the applicable geographic area as a proxy for the allowed charges for the service.

The definition of primary care services at § 425.20 includes CPT codes in the range 99201 through 99205 and 99211 through 99215, and certain other codes. For services furnished prior to January 1, 2014, we use the HCPCS code included on this institutional claim to identify whether the primary care service was rendered to a beneficiary in the same way as for any other claim. However, we implemented a change in coding policy under the Outpatient Hospital Prospective Payment System (OPPS) that inadvertently affects the assignment of beneficiaries to an ACO when the beneficiary receives care at an ETA hospital. Effective for services furnished on or after January 1, 2014, outpatient hospitals, including ETA hospitals, were instructed to use the single HCPCS code G0463 and to no longer use CPT codes in the ranges of 99201 through 99205 and 99211 through 99215. (For example, see our Web site at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8572.pdf,* page 3). In other words, for ETA hospitals, G0463 is a replacement code for CPT codes in the ranges of 99201 through 99205 and 99211 through 99215.

We continue to believe that it is appropriate to use ETA institutional claims for purposes of identifying primary care services furnished by physicians in ETA hospitals and to allow these services to be included in the stepwise methodology for assigning beneficiaries to ACOs. We believe including these claims increases the accuracy of the assignment process by helping ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care. ETA hospitals are often located in underserved areas and serve as providers of primary care for the beneficiaries they serve. Therefore, we are proposing to consider HCPCS code G0463 when submitted by ETA hospitals as a code designated by us as a primary care service for purposes of the Shared Savings Program. We recently updated our existing operational guidance on this issue so that we can continue to consider services furnished in ETA hospitals for beneficiary assignment purposes using the new G code until we codify a change to our definition of primary care services. This approach will allow us to continue to accurately assign Medicare FFS beneficiaries based on their utilization of primary care services furnished by ACO professionals, including those ACOs that may include ETA hospitals.

We would note that in order to promote flexibility for the Shared Savings Program and to allow the definition of primary care services used in the Shared Savings Program to respond more quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process, we recently adopted a policy of making revisions to the definition of primary care service codes for the Shared Savings Program through the annual PFS rulemaking process, and we amended the definition of primary care services at § 425.20 to include additional codes designated by CMS as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT codes or revenue codes and any subsequently modified or replacement codes. Therefore, we propose to amend the definition of primary care services at § 425.20 by adding HCPCS code G0463 for services furnished in an ETA hospital to the definition of primary care services that will be applicable for performance year 2016 and subsequent performance years.

We also propose to revise § 425.402 by adding a new paragraph (d) to provide that when considering services furnished by physicians in ETA hospitals in the assignment methodology, we would use an estimated amount based on the amounts payable under the PFS for similar services in the geographic location in which the ETA hospital is located as a proxy for the amount of the allowed charges for the service. In this case, because G0463 is not payable under the PFS, we are proposing to use the weighted mean amount payable under the PFS for CPT codes in the range 99201 through 99205 and 99211 through 99215 as a proxy for the amount of the allowed charges for HCPCS code G0463 when submitted by ETA hospitals. The weights needed to impute the weighted mean PFS payment rate for HCPCS code G0463 would be derived from the relative number of services furnished at the national level for CPT codes 99201 through 99205 and 99211 through 99215. This is consistent with our current practice and guidance and would continue to allow for beneficiaries to be attributed to the ACO responsible for their care. Additional details regarding computation of the proxy amount for G0463 would be provided through sub-regulatory guidance.

In addition, because we are able to consider claims submitted by ETA hospitals as part of the assignment process, we also propose to amend § 425.102(a) to add ETA hospitals to the list of ACO participants that are eligible to form an ACO that may apply to participate in the Shared Savings Program.

M. 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 program continues CMS's initiative to increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.[9]

2. Governing Principles for VM Implementation.

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 and list those principles here for reference.

- *A focus on measurement and alignment.* Measures for the VM should consistently reflect differences in performance among groups or solo practitioners, reflect the diversity of services furnished, and should be consistent with the National and CMS Quality Strategies and other CMS quality initiatives, including PQRS, the Medicare Shared Savings Program (Shared Savings Program), and the Medicare EHR Incentive Program.

- *A focus on physician and eligible professional choice.* Physicians and other nonphysician EPs should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting EPs' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.

- *A focus on shared accountability.* The VM can facilitate shared accountability by assessing performance at the group level and by focusing on the total costs of care, not just the costs of care furnished by an individual professional.

- *A focus on actionable information.* The Quality and Resource Use Reports (QRURs) should provide meaningful and actionable information to help groups and solo practitioners identify clinical, efficiency and effectiveness areas where they are doing well, as well as areas in which performance could be improved by providing groups and solo practitioners with QRURs on the quality and cost of care they furnish to their patients.

- *A focus on a gradual implementation.* The VM should focus initially on identifying high and low performing groups and solo practitioners. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

[9] Kate Goodrich, et al. ''A History and a Vision for CMS Quality Measurement Programs''. Joint Comm'n J. Quality & Patient Safety. 2012. 38,465, *available at http://www.ingentaconnect.com/content/jcaho/jcjqs/2012/00000038/00000010/art00006.*

3. Overview of Existing Policies for the Physician VM.

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. We also finalized that beginning in January 1, 2018, the VM will apply to nonphysician EPs in groups with 2 or more EPs and to nonphysician EPs who are solo practitioners.

4. Provisions of This Proposed Rule

As a general summary, we are proposing the following VM policies:

- Beginning with the CY 2016 payment adjustment period, a TIN's size would be determined based on the lower of the number of EPs indicated by the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)-generated list or our analysis of the claims data for purposes of determining the payment adjustment amount under the VM.
- For the CY 2018 payment adjustment period, to apply the VM to nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups and those who are solo practitioners, and not to other types of professionals who are nonphysician EPs.
- For the CY 2018 payment adjustment period, to identify TINs as those that consist of nonphysician EPs if either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of nonphysician EPs and no physicians.
- For the CY 2018 payment adjustment period, to not apply the VM to groups and solo practitioners if either the PECOS-generated list or claims analysis shows that the groups and solo practitioners consist only of nonphysician EPs who are not PAs, NPs, CNSs, and CRNAs.
- To continue apply a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners.
- For the CY 2018 payment adjustment period, to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. Groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comments period (79 FR 67937), that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018.
- Beginning with the CY 2017 payment adjustment period, to apply the VM adjustment percentage for groups and solo practitioners that participate in two or more ACOs during the applicable performance period based on the performance of the ACO with the highest quality composite score.
- For the CY 2018 payment adjustment period, to apply the VM for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period as described under § 414.1210(b)(2), regardless of whether any EPs in the group or the solo practitioner also participated in an Innovation Center model during the performance period.
- For the CY 2018 payment adjustment period, if the ACO does not successfully report quality data as required by the Shared Savings Program, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM and will be subject to a downward payment adjustment.
- Beginning in the CY 2017 payment adjustment period, to apply an additional upward payment adjustment of +1.0x to Shared Savings ACO Program participant TINs that are classified as ''high quality'' under the quality-tiering methodology, if the ACOs in which the TINs participated during the performance period have an attributed patient population that has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined under the VM methodology.
- Beginning with the CY 2017 payment adjustment period, to waive application of the VM for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO Model, CPC Initiative, or other similar Innovation Center models during the performance period.
- To set the maximum upward adjustment under the quality-tiering methdology for the CY 2018 VM to +4.0 times an upward payment adjustment factor (to be determined after the performance period has ended) for groups with 10 or more EPs; +2.0 times an adjustment factor for groups with between 2 to 9 EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.
- To set the amount of payment at risk under the CY 2018 VM to 4.0 percent for groups with 10 or more EPs, 2 percent for groups with between 2 to 9 EPs and physician solo practitioners, and 2 percent for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.
- To not recalculate the VM upward payment adjustment factor after it is made public unless there was a significant error made in the calculation of the adjustment factor.
- To use CY 2016 as the performance period for the CY 2018 VM.
- To align the quality measures and quality reporting mechanisms for the CY 2018 VM with those available to groups and individuals under the PQRS during the CY 2016 performance period.
- To separately benchmark the PQRS electronic clinical quality measures (eCQMs) beginning with the CY 2018 VM.
- To include Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surveys in the VM for Shared Savings Program ACOs beginning with the CY 2018 VM.
- To apply the VM to groups for which the PQRS program removes individual EPs from that program's unsuccessful participants list beginning with the 2016 VM.
- Beginning with the CY 2017 payment adjustment period, to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes.
- Beginning with the 2018 VM, to include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM program.
- Beginning in the CY 2016 payment adjustment period, a group or solo

practitioner subject to the VM would receive a quality composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one quality measure that meets the minimum number of cases required for the measure to be included in the calculation of the quality composite.

- To make technical changes to § 414.1255 and § 414.1235.

We also seek comment on, but make no proposals regarding stratifying cost measure benchmarks by beneficiary risk score.

a. Group Size

The policies to identify groups and solo practitioners that are subject to the VM during a specific payment adjustment period are described in § 414.1210(c). Beginning with the CY 2016 payment adjustment period, the list of groups and solo practitioners subject to the VM is based on a query of the PECOS that occurs within 10 days of the close of the PQRS group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on our analysis of claims, the group did not have the required number of EPs that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable CY payment adjustment period. In the CY 2013 PFS final rule with comment period, we stated that for the CY 2015 payment adjustment period, we will not add groups to the PECOS-generated list based on the analysis of claims (77 FR 69309 through 69310). In the CY 2014 PFS final rule with comment period, we finalized that we will continue to follow this procedure for the CY 2016 payment adjustment period and subsequent adjustment period (78 FR 74767).

In the CY 2014 PFS final rule with comment period (78 FR 74767 to 74771), we established different payment adjustment amounts under the 2016 VM for (1) groups with between 10 to 99 EPs, and (2) groups with 100 or more EPs. Similarly, in the CY 2015 PFS final rule with comment period (79 FR 67938 to 67941 and 67951 to 67954), we established different payment adjustment amounts under the 2017 VM for: (1) Groups with between 2 to 9 EPs and physician solo practitioners; and (2) groups with 10 or more EPs. However, we have not addressed how we would handle scenarios where the size of a TIN as indicated on the PECOS-generated list is not consistent with the size of the TIN based on our analysis of the claims data. Therefore, we propose that, beginning with the CY 2016 payment adjustment period, the TIN's size would be determined based on the lower of the number of EPs indicated by the PECOS-generated list or by our analysis of the claims data for purposes of determining the payment adjustment amount under the VM. In the event that our analysis of the claims data indicates that a TIN had fewer EPs during the performance period than indicated by the PECOS-generated list, and the TIN is still subject to the VM based on its size, then we would apply the payment adjustment amount under the VM that is applicable to the size of the TIN as indicated by our analysis of the claims data. In the event that our analysis of the claims data indicates that a TIN had more EPs during the performance period than indicated by the PECOS-generated list, then we would apply the payment adjustment amount under the VM that is applicable to the size of the TIN as indicated by the PECOS-generated list.

For example, for the CY 2016 payment adjustment period, if the PECOS list indicates that a TIN had 100 EPs in the CY 2014 performance period, but our analysis of claims shows that the TIN had 90 EPs based in CY 2014, then we would apply the payment policies to the TIN that are applicable to groups with between 10 to 99 EPs, instead of the policies applicable to groups with 100 or more EPs. Alternatively, if the PECOS list indicates that a TIN had 90 EPs in the CY 2014 performance period, but our analysis of claims shows that the TIN had 100 EPs based in CY 2014, then we would apply the payment policies to the TIN that are applicable to groups with between 10 to 99 EPs, instead of the policies applicable to groups with 100 or more EPs. We propose to update § 414.1210(c) accordingly.

In section III.M.4.b. of this proposed rule, we propose to apply the VM in the CY 2018 payment adjustment period to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups with two or more EPs and to those who are solo practitioners. In section III.M.4.f. of this proposed rule, we propose to apply different payment adjustment amounts under the CY 2018 VM based on the composition of a group. Specifically, in that section we propose that the PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs (in other words, groups that do not include any physicians) and those who are solo practitioners would be subject to different payment adjustment amounts under the CY 2018 VM than would groups composed of physicians and nonphysician EPs and physician solo practitioners. We propose to identify TINs that consist of nonphysician EPs as those TINs for which either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of nonphysician EPs and no physicians. We note that under our proposal the VM would only apply to the PAs, NPs, CNSs, and CRNAs who bill under these TINs, and not to the other types of nonphysician EPs who may also bill under these TINs. We propose that the VM would not apply to a TIN if either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of only nonphysician EPs who are *not* PAs, NPs, CNSs, and CRNAs. The following examples illustrate these proposals. If the PECOS-generated list shows that a TIN consists of physicians and NPs and the claims data show that only NPs billed under the TIN, then we would apply the payment adjustments proposed in section III.M.4.f. of this proposed rule that are applicable to PAs, NPs, CNSs, and CRNAs in TINs that consist of nonphysician EPs. If the PECOS-generated list shows that a TIN consists of PAs, NPs, CNSs, or CRNAs, and no physicians, and the claims data show that the TIN also consists of physicians, then we would apply the payment adjustments applicable to PAs, NPs, CNSs, and CRNAs in TINs that consist of nonphysician EPs. This would be consistent with our policy to apply the payment adjustments applicable to the lower group size when there is a discrepancy in the group size between PECOS and claims analysis, in that it would result in the group being subject to the lower amount at risk and lower possible upward payment adjustment, when there is a difference between the PECOS and claims analyses.

If the PECOS-generated list shows that a TIN consists of physicians and the claims data shows, for example, that PAs and physicians billed under the TIN, then we would apply the payment adjustments proposed in section III.M.4.f. of this proposed rule for TINs with physicians and nonphysician EPs depending on the size of the TIN. If the PECOS-generated list shows, for example, that a TIN consists of PAs and the claims data shows that only physical therapists billed under the group, then the TIN would not be subject to the VM in CY 2018. Conversely, if the PECOS-generated list shows, for example, that a TIN consists of physical therapists and the claims data shows that only PAs

billed under the group, then the TIN would not be subject to the VM in CY 2018. We welcome public comment on these proposals. We propose to revise § 414.1210(c) accordingly.

b. Application of the VM to Nonphysician EPs Who Are PAs, NPs, CNSs, and CRNAs

Section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to EPs as defined in section 1848(k)(3)(B) of the Act. In the CY 2015 PFS final rule with comment period (79 FR 67937), we finalized that we will apply the VM beginning in the CY 2018 payment adjustment period to nonphysician EPs in groups with two or more EPs and to nonphysician EPs who are solo practitioners. We added § 414.1210(a)(4) to reflect this policy. Under this policy, we will apply the VM beginning in CY 2018 to the items and services billed under the PFS by all of the physicians and nonphysician EPs who bill under a group's TIN. Beginning in CY 2018, the VM will apply to all of the EPs, as specified in section 1848(k)(3)(B) of the Act, that bill under a group's TIN based on the TIN's performance during the applicable performance period. During the payment adjustment period, all of the nonphysician EPs who bill under a group's TIN will be subject to the same VM that will apply to the physicians who bill under that TIN. We finalized the modification to the definition of ''group of physicians'' under § 414.1205 to also include the term ''group'' to reflect these policies. Additionally, we finalized that beginning in CY 2018, physicians and nonphysician EPs will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician EPs will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We finalized modifications to the regulations under subpart N accordingly.

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. Under section 1848(q)(1)(C)(i)(I) of the Act, with regard to payments for items and services furnished in 2019 and 2020, the MIPS will only apply to:

- A physician (as defined in section 1861(r) of the Act);
- A PA, NP, and CNS (as defined in section 1861(aa)(5) of the Act);
- A CRNA (as defined in section 1861(bb)(2) of the Act); and
- A group that includes such professionals.

Then, under section 1848(q)(1)(C)(i)(II) of the Act, beginning with payments for items and services furnished in 2021, the MIPS will apply to such other EPs as defined in section 1848(k)(3)(B) of the Act as specified by the Secretary. As noted above, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to EPs as defined in section 1848(k)(3)(B) of the Act. In the CY 2015 PFS final rule with comment period (79 FR 67937), we finalized that we will apply the VM beginning in the CY 2018 payment adjustment period to all nonphysician EPs in groups with two or more EPs and to nonphysician EPs who are solo practitioners. However, after the enactment of MACRA in April 2015, we believe it would not be appropriate to apply the VM in CY 2018 to any nonphysician EP who is not a PA, NP, CNS, or CRNA since payment adjustments under the MIPS would not apply to them until 2021. Therefore, we propose to apply the VM in the CY 2018 payment adjustment period to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups with two or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners. We propose to revise § 414.1210(a)(4) to reflect this proposed policy. We propose to define PAs, NPs, and CNSs as defined in section 1861(aa)(5) of the Act and to define CRNAs as defined in section 1861(bb)(2) of the Act. We propose to add these definitions under § 414.1205.

Under our proposal, we would apply the VM in CY 2018 to the items and services billed under the PFS by all of the PAs, NPs, CNSs, and CRNAs who bill under a group's TIN based on the TIN's performance during the applicable performance period. We note that the VM would not apply to other types of nonphysician EPs (that is, nonphysician EPs who are not PAs, NPs, CNSs, or CRNAs) who may also bill under the TIN.

As noted above, we finalized in the CY 2015 PFS final rule with comment period (79 FR 67937) that beginning in CY 2018, all of the nonphysician EPs who bill under a group's TIN will be subject to the same VM that will apply to the physicians who bill under that TIN, and physicians and nonphysician EPs will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician EPs who are in groups containing one or more physicians will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We are not proposing to revise these policies; however, we note that if a group is composed of physicians and nonphysician EPs, only the physicians and the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs would be subject to the VM in CY 2018.

In the CY 2015 PFS final rule with comment period (79 FR 67937), we also finalized that we will apply the VM beginning in CY 2018 to groups that consist only of nonphysician EPs (for example, groups with only NPs or PAs) and to nonphysician EPs who are solo practitioners. However, since CY 2018 will be the first year that groups that consist only of nonphysician EPs and solo practitioners who are nonphysician EPs will be subject to the VM, we finalized a policy to hold these groups and solo practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. We stated that we will add regulation text under § 414.1270 to reflect this policy when we establish the policies for the VM for the CY 2018 payment adjustment period in future rulemaking. Accordingly, we propose to add § 414.1270(d) to codify that PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. In section III.M.4.f. of this proposed rule, we discuss the proposed CY 2018 payment adjustment amounts for groups that consist of nonphysician EPs and solo practitioners who are nonphysician EPs that fall in Category 1 and Category 2 for the CY 2018 VM. As discussed above, we are proposing to apply the VM in CY 2018 only to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

c. Approach to Setting the VM Adjustment Based on PQRS Participation

Section 1848(p)(4)(B)(iii)(II) of the Act requires the Secretary to apply the VM to items and services furnished under the PFS beginning not later than January 1, 2017, for all physicians and groups of physicians. Therefore, in the CY 2015 PFS final rule with comment period (79 FR 67936), 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. In the CY 2015 PFS

final rule with comment period (79 FR 67938 to 67939), we adopted a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. For purposes of the CY 2017 VM, we finalized that Category 1 includes those groups that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHR, or registry reporting mechanism) for the CY 2017 PQRS payment adjustment. We finalized that Category 1 also includes groups that do not register to participate in the PQRS as a group practice participating in the PQRS GPRO in CY 2015 and that have at least 50 percent of the group's EPs meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR, or registry reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry (QCDR) for the CY 2017 PQRS payment adjustment. Lastly, we finalized that Category 1 includes those solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, registry, or EHR reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the CY 2017 PQRS payment adjustment. We finalized that Category 2 includes those groups and solo practitioners that are subject to the CY 2017 VM 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 with 10 or more EPs and −2.0 percent for groups with between 2 to 9 EPs and solo practitioners.

We propose to use a similar two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. However, we note that during the 2014 PQRS submission period, we received feedback from groups who experienced difficulty reporting through the reporting mechanism they had chosen at the time of 2014 PQRS GPRO registration. For example, some groups registered for the group EHR reporting mechanism and were subsequently informed that their EHR vendor could not support submission of group data for the group EHR reporting mechanism. To address these concerns and continue to accommodate the various ways in which EPs and groups can participate in the PQRS, for purposes of the CY 2018 VM, we propose that Category 1 would include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO, as proposed in table 21 of this proposed rule. We also propose to include in Category 1 groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals, as proposed in table 20 of this proposed rule. We propose to add corresponding regulation text to § 414.1270(d)(1).

We note that the proposed criteria for groups to be included in Category 1 for the CY 2018 VM differ from the criteria we finalized for the CY 2017 VM in the CY 2015 PFS final rule with comment period. Under the policy for the CY 2017 VM, we would only consider whether at least 50 percent of a group's EPs met the criteria to avoid the PQRS payment adjustment as individuals if the group did not register to participate in a PQRS GPRO. In contrast, under our proposal for the CY 2018 VM, in determining whether a group would be included in Category 1, we would consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO. We believe this proposal would 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 purposes of applying the CY 2018 VM.

We also propose to revise the criteria for groups to be included in Category 1 for the CY 2017 VM, if it is operationally feasible for our systems to utilize data reported through a mechanism other than the one through which a group registered to report under PQRS GPRO. At this time, it is unclear whether CMS systems can support this type of assessment as soon as the CY 2017 VM, and thus our proposal is contingent upon operational feasibility. For the CY 2017 VM, we propose that Category 1 would 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 also propose to include in Category 1 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. We propose that if operationally feasible, we would apply these criteria to identify which groups would fall in Category 1 for the CY 2017 VM regardless of whether or how the group registered to participate in the PQRS as a group practice in CY 2015. If our systems are not able to accomplish this, then we will apply our existing policy for the CY 2017 VM, as finalized in the CY 2015 PFS final rule with comment period (79 FR 67938 through 67939), to consider whether at least 50 percent of a group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals only in the event that the group did not register to report as a group under the PQRS GPRO. We seek comments on these proposals.

Lastly, we propose to include in Category 1 for the CY 2018 VM those solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, as proposed in table 20 of this proposed rule.

Category 2 would include those groups and solo practitioners that are subject to the CY 2018 VM and do not fall within Category 1. As discussed in section III.M.4.f. of this proposed rule, we are proposing to apply the following VM adjustment to payments for groups and solo practitioners that fall in Category 2 for the CY 2018 VM: A −4.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs; a −2.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and to physician solo practitioners; and a −2.0 percent VM to PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs. As discussed in section III.M.4.b. of this proposed rule, we propose to apply the VM in CY 2018 to the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs. We seek comment on these proposals.

For a group or solo practitioner that would be subject to the CY 2018 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of solo practitioners and the 50 percent option described above for groups) would need to be met during the reporting periods occurring in CY 2016 for the CY 2018 PQRS payment adjustment. In section III.M.4.h. of this proposed rule, we propose to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. In the event that the criteria that are finalized for the CY 2018 PQRS payment adjustment differ from what is proposed for the PQRS in this proposed rule, our intention is to align the criteria for inclusion in Category 1 to the extent possible with the criteria that are

ultimately established for the CY 2018 PQRS payment adjustment.

In the CY 2015 PFS final rule with comment period (79 FR 67939 to 67941), we finalized that the quality-tiering methodology will apply to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with between 2 to 9 EPs and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more EPs would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, groups with between 2 to 9 EPs and solo practitioners in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM.

As stated earlier in this proposed rule, in CY 2018, the same VM would apply to all of the physicians, PAs, NPs, CNSs, and CRNAs who bill under a TIN. The VM would not apply to other types of nonphysician EPs who may also bill under the TIN. For the CY 2018 VM, we propose to continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We propose that groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comments period (79 FR 67937), that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. Based on our proposal to apply the CY 2018 VM only to certain types of nonphysician EPs, only the PAs, NPs, CNSs, and CRNAs in groups consisting of nonphysician EPs and those who are solo practitioners will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. We propose to revise § 414.1270 to reflect these proposals. We seek comments on these proposals. In section III.M.4.f. of this proposed rule, we discuss the proposed CY 2018 payment adjustment amounts for groups and solo practitioners that fall in Category 1 and Category 2 for the CY 2018 VM.

For groups with between 2 to 9 EPs and physician solo practitioners, we believe it is appropriate to begin both the upward and downward payment adjustments under the quality-tiering methodology for the CY 2018 VM. As stated in the CY 2015 PFS final rule with comment period (79 FR 67935), in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how all TINs fare under the policies established for the VM for the CY 2015 payment adjustment period. As discussed in section III.M.5.a. of this proposed rule, in April 2015, we made available 2014 Mid-Year QRURs to groups of physicians and physician solo practitioners nationwide. The Mid-Year QRURs provide interim information about performance on the claims-based quality outcome measures and cost measures that are a subset of the measures that will be used to calculate the CY 2016 VM and are based on performance from July 1, 2013 through June 30, 2014. Then, during the Fall of 2015, we intend to disseminate QRURs based on CY 2014 data to all groups and solo practitioners, and the reports would show all TINs their performance during CY 2014 on all of the quality and cost measures that will be used to calculate the CY 2016 VM. Thus, we believe groups with between 2 to 9 EPs and physician solo practitioners will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2018. We note that the quality and cost measures in the QRURs that these groups will receive are similar to the measures that will be used to calculate the CY 2018 VM. In addition, we believe that these groups and solo practitioners have had sufficient time to understand how the VM works and how to participate in the PQRS. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with between 2 to 9 EPs and physician solo practitioners in CY 2018.

We will continue to monitor the VM program and continue to examine in the VM Experience Report the characteristics of those groups and solo practitioners that would be subject to an upward or downward payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

d. Application of the VM to Physicians and Nonphysician EPs Who Participate in ACOs Under the Shared Savings Program

In the CY 2015 PFS final rule with comment period, we finalized a policy to apply the VM, beginning with the CY 2017 payment adjustment period, to physicians in groups with two or more EPs and physicians who are solo practitioners that participate in an ACO under the Shared Savings Program, and beginning with the CY 2018 payment adjustment period, to nonphysician EPs in groups with two or more EPs and nonphysician EPs who are solo practitioners that participate in an ACO under the Shared Savings Program. We finalized that the determination of whether a group or solo practitioner is considered to be in an ACO under the Shared Savings Program would be based on whether that group or solo practitioner, as identified by TIN, was an ACO participant in the performance period for the applicable payment adjustment period for the VM. For groups and solo practitioners determined to be ACO participants, we finalized a policy that we would classify the group or solo practitioner's cost composite as ''average'' and calculate its quality composite based on the quality-tiering methodology using quality data submitted by the Shared Savings Program ACO for the performance period and apply the same quality composite to all of the groups and solo practitioners, as identified by TIN, under that ACO. For further explanation of the final policies for applying the VM to ACO participants in Shared Savings Program ACOs, we refer readers to 79 FR 67941 through 67947 and 67956 through 67957.

(1) Application of the VM to Groups and Solo Practitioners Who Participate in Multiple Shared Savings Program ACOs

Under the Shared Savings Program regulations (§ 425.306(b)), an ACO participant TIN upon which beneficiary assignment is dependent may only participate in one Shared Savings Program ACO. ACO participant TINs that do not bill for primary care services, however, are not required to be exclusive to one Shared Savings Program ACO. As a result, there are a small number of TINs that are ACO participants in multiple Shared Savings Program ACOs. We did not previously address how the VM will be applied to these TINs.

Beginning with the CY 2017 payment adjustment period, we propose that TINs that participate in multiple Shared Savings Program ACOs in the applicable

performance period would receive the quality composite score of the ACO that has the highest numerical quality composite score. For this determination, we will only consider the quality data of an ACO that completes quality reporting under the Shared Savings Program. We propose to apply this policy in situations where the VM is determined based on quality-tiering or the ACO's failure to successfully report quality data as required by the Shared Savings Program. Below are several examples to illustrate the proposal:

Example A: TIN A participates in ACO 1 and ACO 2 in the 2015 performance period. ACO 1 fails to complete quality reporting under the Shared Savings Program as required under § 425.504(a)(1), and therefore, the ACO 1 participants would be classified as Category 2 and subject to the automatic downward adjustment under the VM. ACO 2 completes quality reporting as required under § 425.504(a)(1), and applying the quality-tiering methodology as described at § 414.1210(b)(2)(i)(B) using ACO 2's quality data, the TIN would be classified as average quality. Under our proposal, TIN A would receive a neutral (0 percent) VM in 2017 based on a quality composite determined using ACO 2's quality reporting and a cost composite of average.

Example B: TIN B participates in ACO 2 and ACO 3 in the 2015 performance period. ACO 2 and ACO 3 complete quality reporting under the Shared Savings Program, and ACO 3 has a higher numerical quality composite score than ACO 2. Under our proposal, TIN B would receive a VM in 2017 based on a quality composite determined using ACO 3's quality reporting and a cost composite of average.

Example C: TIN C participates in ACO 1 and ACO 4 in the 2015 performance period. Both ACO 1 and ACO 4 fail to complete quality reporting under the Shared Savings Program. TIN C would still be classified as Category 2 and would receive an automatic downward adjustment because both ACOs failed to report. This scenario is not affected by our proposal.

Under the VM, any TIN's quality composite score must be at least one standard deviation away from and statistically significantly different from the mean, for it to be classified as other than average quality (77 FR 69325). Because of this requirement, it is possible for any TIN's quality composite to be categorized as ''average,'' due to its being either within one standard deviation of the mean or not statistically significant from it. Similarly, it is possible that including performance data for the ACO with the higher quality composite score in a given TIN's VM calculation would not result in a higher VM adjustment percentage than would inclusion of data from another ACO with a lower quality composite score that is also at least 1 standard deviation away from the mean. Given the requirement that a Shared Savings Program ACO must have at least 5,000 assigned beneficiaries, we do not expect that this situation is likely to occur, though it is possible. The following example illustrates how this situation could occur:

Example D: TIN B participates in ACO 2 and ACO 3 in the 2015 performance period. ACO 2 completes quality reporting and the quality composite score using ACO 2's quality data is two standard deviations below the mean but is not statistically below the mean, in the sense of being both below the mean and statistically significantly different from the mean. Under § 414.1275(b)(1), the quality composite score would be classified as average because it is not statistically below the mean. ACO 3 completes quality reporting and the quality composite score using ACO 3's quality data is one and a half standard deviations below the mean and, is statistically significantly below the mean. Under § 414.1275(b)(1), the quality composite score would be classified as low. The quality composite score that is one and a half standard deviations below the mean is numerically higher than the quality composite score that is two standard deviations below the mean, so under our proposal, TIN B would receive a negative VM in 2017 based on a quality composite determined using ACO 3's quality reporting and a cost composite of average.

We believe our proposed approach is appropriate because it is straightforward for TINs participating in multiple Shared Savings Program ACOs to understand. The proposed policy is transparent and would allow Shared Savings Program ACO participant TINs the ability to compare the performance of the highest-performing ACO in which they participate to national benchmarks. Given that we did not make proposals for applying the VM to these TINs prior to the start of the 2015 performance period for the 2017 VM, we do not believe it would be fair to give ACO participants in multiple Shared Savings Program ACOs the lower of the quality composite scores for which they may have been eligible. We propose to make corresponding changes to § 414.1210(b)(2). We are seeking comment on this proposal.

In developing this proposed policy, we considered several alternative options. We considered proposing that the above policy would apply as long as all ACOs in which the TIN participates complete reporting under the Shared Savings Program. If one of the ACOs failed to report, the TIN would be categorized as Category 2 even though it participated in another ACO that successfully reported. We believe this would create unnecessary complexity and would not be fair to TINs that were not made aware of this policy prior to the start of the CY 2015 performance period for the 2017 payment adjustment period. We also considered proposing a policy under which the TIN would be required to indicate which ACO it wanted to be associated with for purposes of the VM. We did not make this proposal because we believed it created additional operational complexity for the TINs and us, and would put the TIN in a position of having to predict which ACO would perform better under the VM, which we do not believe would be appropriate. We welcome feedback on these alternatives we considered.

(2) Application of VM to Participant TINs in Shared Savings Program ACOs That Also Include EPs Who Participate in Innovation Center Models

Under the Shared Savings Program statute and regulations, ACO participants may not participate in another Medicare initiative that involves shared savings payments (§ 425.114(b)). However, there are Medicare initiatives, including models authorized by the Innovation Center, that do not involve shared savings payments, and in some cases a TIN that is a Shared Savings Program participant may also include EPs who participate in an Innovation Center model. Because the Shared Savings Program identifies participants by a TIN and many Innovation Center models allow some EPs under a TIN to participate in the model while other EPs under that TIN do not, we believe it is more appropriate to apply the VM policies finalized for Shared Savings Program participants to these TINs than to apply the policies for Innovation Center models proposed in section III.M.4.e. of this proposed rule. We are proposing that, beginning with the 2017 payment adjustment period for the VM, we would determine the VM for groups and solo practitioners (as identified by TIN) who participated in a Shared Savings Program ACO in the performance period in accordance with the VM policies for Shared Savings Program participants under § 414.1210(b)(2), regardless of whether any EPs under the TIN also participated in an Innovation Center model during the performance period. We propose to make corresponding changes to § 414.1210(b)(2)(i)(E). We are seeking comment on this proposal.

(3) Application of VM to Participant TINs in Shared Savings Program ACOs That Do Not Complete Quality Reporting

In the CY 2015 PFS proposed rule, we did not specifically address the scenario in which a Shared Savings Program ACO does not successfully report on

quality as required under the Shared Savings Program during the performance period for the VM. We clarified in the CY 2015 PFS final rule with comment period that we intended to adopt for groups and solo practitioners that participate in a Shared Savings Program ACO 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 (79 FR 67946). 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 at § 414.1210(b)(2)(i)(C). We propose to continue this policy in the CY 2018 payment adjustment period for all groups and solo practitioners subject to the VM, including groups composed of nonphysician EPs and solo practitioners who are nonphysician EPs. We propose corresponding revisions to § 414.1210(b)(2)(i)(D). This 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. We are seeking comment on this proposal.

(4) Application of an Additional Upward Payment Adjustment to High Quality Participant TINs in Shared Savings Program ACOs for Treating High-Risk Beneficiaries

In the CY 2015 PFS final rule with comment period, we finalized in the regulation text at § 414.1275(d)(2) that groups and solo practitioners that are classified as high quality/low cost, high quality/average cost, or average quality/low cost under the quality-tiering methodology for the CY 2017 payment adjustment period would receive an additional upward payment adjustment of +1.0x, if their attributed patient population has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide. We are proposing a similar policy for the CY 2018 payment adjustment period as discussed in section III.M.4.f. of this proposed rule.

Beginning in the CY 2017 payment adjustment period, we propose to apply a similar additional upward adjustment to groups and solo practitioners that participated in high performing Shared Savings Program ACOs that cared for high-risk beneficiaries (as evidenced by the average HCC risk score of the ACO's attributed beneficiary population as determined under the VM methodology) during the performance period. We finalized in the CY 2015 PFS final rule with comment period that the quality composite score for TINs that participated in Shared Savings Program ACOs during the performance period will be calculated using the quality data reported by the ACO through the ACO GPRO Web Interface and the ACO all-cause hospital readmission measure, and the cost composite will be classified as ''average'' (79 FR 67941 through 67947). We believe this policy would be appropriate because attribution on the quality measures used in the VM calculation for Shared Savings Program ACO TINs is done at the ACO level. Further, under the Shared Savings Program ACO participants are responsible for coordinating the care of beneficiaries assigned to the ACO, so it is appropriate to determine whether those beneficiaries are in the highest risk category, at the ACO level. Therefore, beginning in the CY 2017 payment adjustment period, we propose to apply an additional upward payment adjustment of +1.0x to Shared Savings Program ACO participant TINs that are classified as ''high quality'' under the quality-tiering methodology, if the attributed patient population of the ACO in which the TINs participated during the performance period has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined under the VM methodology. We propose corresponding revisions to the regulation text at § 414.1210(b)(2). We are seeking comment on this proposal.

In the CY 2015 PFS proposed rule (79 FR 40500), we proposed that groups and solo practitioners participating in ACOs under the Shared Savings Program would be eligible for the additional upward payment adjustment +1.0x for caring for high-risk beneficiaries; however, the proposal was not finalized in the CY 2015 PFS final rule with comment period. We note that our proposal above is based on using the ACO's assigned beneficiary population; whereas, our proposal in the CY 2015 PFS Proposed Rule was based on using the group or solo practitioner's attributed beneficiary population.

e. Application of the VM to Physicians and Nonphysician EPs That Participate in the Pioneer ACO Model, the CPC Initiative, or Other Similar Innovation Center Models or CMS Initiatives

We established a policy in the CY 2013 PFS final rule with comment period (77 FR 69313) to not apply the VM in the CY 2015 and CY 2016 payment adjustment periods to groups of physicians that participate in Shared Savings Program ACOs, the Pioneer ACO Model, the Comprehensive Primary Care (CPC) initiative, or other similar Innovation Center models or CMS initiatives. We stated in the CY 2014 PFS final rule with comment period (78 FR 74766) that from an operational perspective, we will apply this policy to any group of physicians that otherwise would be subject to the VM, if one or more physician(s) in the group participate(s) in one of these programs or initiatives during the relevant performance period (CY 2013 for the CY 2015 payment adjustment period, and CY 2014 for the CY 2016 payment adjustment period). In the CY 2015 PFS final rule with comment period (79 FR 67949), we finalized a policy that for solo practitioners and groups subject to the VM with at least one EP participating in the Pioneer ACO Model or CPC Initiative during the performance period, we will classify the cost composite as ''average cost'' and the quality composite as ''average quality'' for the CY 2017 payment adjustment period. We did not finalize a policy for any payment adjustment period after CY 2017. We believed this policy was appropriate because it would enable groups and solo practitioners participating in these Innovation Center models to focus on the goals of the models and would minimize the risk of potentially creating conflicting incentives with regard to the evaluation of the quality and cost of care furnished for the VM and evaluation of cost and quality under these models. In addition, given that these models include groups in which some EPs participate in the model and others do not participate, it is challenging to meaningfully evaluate the quality of care furnished by these groups.

(1) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in the Pioneer ACO Model and CPC Initiative

We received many comments on the proposals made in the CY 2015 PFS proposed rule indicating that we should exempt Pioneer ACO Model and CPC Initiative participants from the VM. As we noted in response to comments in

the CY 2015 final rule with comment period (79 FR 67947), a few commenters also suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. In considering potential policy options to include in this proposed rule, we agree with the commenters that it would be appropriate to use the waiver authority with regard to the Pioneer ACO Model and CPC Initiative. Accordingly, under section 1115A(d)(1) of the Act, we are proposing to waive application of the VM as required by section 1848(p) of the Act for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO Model or CPC Initiative during the performance period. This policy, as well as the use of the waiver authority under section 1115A(d)(1) for this purpose, will no longer apply in CY 2019 when the Value Modifier program is incorporated into the new Merit-based Incentive Payment System. We believe a waiver is necessary to test these models because their effectiveness would be impossible to isolate from the confounding variables of quality and cost metrics and contrasting payment incentives utilized under the VM.

- CPC Initiative: CPC practice sites are assessed on and have the opportunity to receive shared savings based on their quality and cost performance. CPC practice sites are assessed on quality measures at the practice site level and, for utilization measures, at the regional level (all practice sites within a CPC region), rather than at the TIN level as for the VM. The cost evaluation methodology used by the CPC Initiative is significantly different from the cost measures and benchmarks used to calculate the cost composite for the VM. In addition, it is difficult to evaluate the quality of care furnished by groups that participate in the CPC Initiative in order to calculate a quality composite for the VM because the CPC Initiative includes ''split TINs'' (groups where some eligible professionals in the group participate in the model while others do not participate), whereas the VM is applied to an entire TIN. As we noted in the CY 2015 PFS proposed rule (79 FR 40501), we do not believe that we can reasonably use the quality data submitted under the CPC Initiative for purposes of calculating a quality composite score under the VM. For these reasons, we believe it is necessary to waive the VM for purposes of testing the CPC Initiative. We believe a waiver would allow CPC model participants to focus on the aims of and measures assessed in the model, diminish the potential for methodological differences between the model and the VM, and would avoid the potential for inequitable comparisons of cost and quality that could arise as a result of differences between VM and CPC.
- *Pioneer ACO Model:* The Pioneer ACO Model combines two-sided financial risk with quality outcomes. Participants in the Pioneer ACO Model are required to report quality, and their savings or loss determination is affected by their quality score. Similar to the CPC Initiative, the Pioneer ACO Model includes split TINs, and we do not believe that we can reasonably use the quality data reported under the Pioneer ACO Model for purposes of calculating a quality composite score for the VM. The Pioneer ACO Model's methodology for evaluating costs is also significantly different from the VM methodology, which could create conflicting incentives for model participants. We believe a waiver of the VM is necessary to test the Pioneer ACO Model for these reasons. We also note that Pioneer ACOs are in their final performance years of the Model. Changing the quality component of the Model at this stage would confound multiple variables of quality and cost metrics within the model.

We believe we could have waived application of the VM for these models with regard to the CY 2017 payment adjustment period, and we are proposing the waiver would apply beginning with the CY 2017 payment adjustment period. We note that in practice, this proposal would not affect a TIN's payments differently as compared with the current policy for the CY 2017 payment adjustment period. A TIN that is classified as ''average cost'' and ''average quality'' would receive a neutral (0 percent) adjustment, and thus its payments during the CY would not increase or decrease as a result of the application of the VM. We also note that we have established a policy to apply the VM at the TIN level (77 FR 69308–69310), and as a result, this proposed waiver would affect the payments for items and services billed under the PFS for the CY 2017 and 2018 payment adjustment periods for the EPs who participate in the Pioneer ACO Model and the CPC Initiative during the performance period, as well as the EPs who do not participate in one of these models but bill under the same TIN as the EPs who do participate. We are proposing to revise § 414.1210(b)(3) to reflect these proposals. We are seeking comment on these proposals. We continue to explore how to address practices that only have some physicians participating in a model and plan to seek stakeholder input on these 'split TIN' practices and related issues in an upcoming Request for Information.

(2) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in Similar Innovation Center Models

In the CY 2015 PFS final rule with comment period (79 FR 67949–67950), we finalized criteria that we will use to determine if future Innovation Center models or CMS initiatives are ''similar'' to the Pioneer ACO Model and CPC Initiative. We finalized that we will apply the same VM policies adopted for participants in the Pioneer ACO Model and CPC Initiative to groups and solo practitioners who participate in similar Innovation Center models and CMS initiatives. The criteria are: (1) The model or initiative evaluates the quality of care and/or requires reporting on quality measures; (2) the model or initiative evaluates the cost of care and/or requires reporting on cost measures; (3) participants in the model or initiative receive payment based at least in part on their performance on quality measures and/or cost measures; (4) potential for conflict between the methodologies used for the VM and the methodologies used for the model or initiative; or (5) other relevant factors specific to a model or initiative. We noted that a model or initiative would not have to satisfy or address all of these criteria to be considered a similar model or initiative.

We are proposing that in the event we finalize our proposal to waive application of the VM under section 1115A(d)(1) of the Act for the Pioneer ACO Model and CPC Initiative as discussed in the preceding section, we would also waive application of the VM for Innovation Center models that we determine are similar models based on the criteria above and for which we determine such a waiver is necessary for purposes of testing the model in accordance with section 1115A(d)(1) of the Act. For models that we determine are similar and require a waiver, we would waive application of the VM as required by section 1848(p) of the Act for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the model during the performance period. We again note that this policy and use of the waiver

authority under section 1115A(d)(1) would sunset prior to CY 2019 when the VM is replaced by MIPS. We would publish a notice of the waiver in the **Federal Register** and also provide notice to participants in the model through the methods of communication that are typically used for the model. We are proposing to revise § 414.1210(b)(4) to reflect this proposal. We are seeking comment on this proposal.

(a) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in the Comprehensive ESRD Care Initiative, Oncology Care Model, and the Next Generation ACO Model

There are several new Innovation Center models starting in 2015 or 2016, including the Comprehensive ESRD Care Initiative, Oncology Care Model, and the Next Generation ACO Model. We have evaluated these models based on the criteria for ''similar'' models and initiatives described in the preceding section and determined that they are similar to the Pioneer ACO Model and CPC Initiative. We believe a waiver of the VM under section 1115A(d)(1) of the Act is necessary to test these models. These new models may include groups in which some EPs participate in the model and others do not, which will make it challenging to meaningfully calculate the quality and cost composite for these TINs needed for the application of the VM. The following bullets describe these models, including ways in which these models are similar to the Pioneer ACO Model and the CPC Initiative, and provide a brief explanation of our belief that a waiver is necessary to test the models:

- *The Next Generation ACO Model:* The Next Generation ACO Model builds upon CMS ACO initiatives with ACOs taking on even greater financial risk than they have in the Pioneer ACO Model. Next Generation ACOs may receive waivers related to coverage for telehealth services, post-discharge home visits, and skilled nursing without prior hospitalization. The first performance period for this model is 2016, and we want to minimize conflicting incentives with regard to the evaluation of the quality and cost of care furnished for the VM and evaluation of cost and quality under this model.
- *The Oncology Care Model:* The Oncology Care Model (OCM) is an episode-based model that provides an incentive for participating practices to reduce the total cost of care for 6-month episodes triggered by either an initial chemotherapy administration claim or initial Part D chemotherapy claim. The first performance period of this model will start in 2016. OCM will use a set of measures that are specific to oncology and may not be included in existing federal quality reporting programs, such as the PQRS. Additionally, OCM will use a quarterly reporting period that is different than the calendar year performance period for the VM. Due to the specialty-specific measure set and alternative reporting period, we believe that waiving the VM would minimize conflicting incentives between programs with regard to the evaluation of quality of cost and care.
- *The Comprehensive ESRD Care Initiative:* The Comprehensive ESRD Care (CEC) Initiative is planning to start an 18-month performance period in August 2015 and is seeking to use the authority under section 1899(b)(3)(D) of the Act to utilize alternative measures, namely the CEC Initiative quality measure set, to serve as satisfactory reporting for the PQRS program beginning in CY 2016. The use of the alternative CEC measure set would result in insufficient PQRS quality data to reliably calculate a quality composite score for the VM. While the CEC Initiative may have TINs that include non-participants that choose to report separately to the PQRS program, their PQRS data may not be representative of the TIN, and therefore we believe it would be inappropriate for calculating the VM. As with other CMMI models, we believe waiving the application of the VM would minimize conflicting incentives with regard to the evaluation of the quality and cost of care.

We are proposing that in the event we finalize our proposal to waive application of the VM as required by section 1848(p) of the Act under section 1115A(d)(1) of the Act for the Pioneer ACO Model and CPC Initiative, we would also waive application of the VM for the Next Generation ACO Model, the Oncology Care Model, and the Comprehensive ESRD Care Initiative as similar models. Specifically, we would waive application of the VM for the CY 2018 payment adjustment period for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the CY 2016 performance period for the VM participated in the Next Generation ACO Model, the Oncology Care Model, or the Comprehensive ESRD Care Initiative during the CY 2016 performance period. We are seeking comment on this proposal.

(b) Application of VM to Similar CMS Initiatives That Are Not Innovation Center Models

In the CY 2015 PFS final rule with comment period (79 FR 67949–67950), we finalized criteria that we will use to determine if future Innovation Center models or CMS initiatives are ''similar'' to the Pioneer ACO Model and CPC Initiative. We finalized that we will apply the same VM policies adopted for participants in the Pioneer ACO Model and CPC Initiative to groups and solo practitioners who participate in similar Innovation Center models and CMS initiatives. We are proposing in section III.M.4.e.1. of this proposed rule to waive the VM for solo practitioners and groups with at least one EP participating in the Pioneer ACO Model or CPC Initiative under section 1115A(d)(1) of the Act. The waiver authority under section 1115A(d)(1) of the Act does not apply to CMS initiatives that are not Innovation Center models. Therefore, in the event that we finalize the waiver, we propose to remove the references to ''CMS initiatives'' from § 414.1210(b)(4). To the extent that any CMS initiatives that are not Innovation Center models would require alternative policies for application of the VM, we would address those policies through future rulemaking. We are seeking comment on this proposal.

f. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups and solo practitioners based on high performance and decrease for others based on low performance, but the aggregate expected amount of Medicare spending in any given year for physician and nonphysician EP services paid under the Medicare PFS will not change as a result of application of the VM.

In the CY 2015 PFS final rule with comment period (79 FR 67952 to 67954), we finalized that we will apply a −2.0 percent VM to groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 2 for the CY 2017 VM. We also finalized that the maximum upward adjustment under the quality-tiering methodology in CY 2017 for groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 1 will be +2.0x if a group or solo practitioner is classified as high quality/low cost and +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. These groups and solo practitioners will be held harmless from any downward adjustments under the quality-tiering methodology in CY 2017,

if classified as low quality/high cost, low quality/average cost, or average quality/high cost.

For groups with 10 or more EPs, we finalized for CY 2017 that we will apply a −4.0 percent VM to a group that falls in Category 2. In addition, we finalized that we will set the maximum downward adjustment under the quality-tiering methodology in CY 2017 to −4.0 percent for groups with 10 or more EPs classified as low quality/high cost and set the adjustment to −2.0 percent for groups classified as either low quality/average cost or average quality/high cost. We finalized that we will also set the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups with 10 or more EPs classified as high quality/low cost and set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. We also finalized that we will continue to provide an additional upward payment adjustment of +1.0x to groups with two or more EPs and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population).

As noted in section III.M.4.b. of this proposed rule, under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019. To maintain stability in the payment adjustment amounts applicable under the VM as we transition to the MIPS in 2019, we propose to maintain the payment adjustment amounts in CY 2018 that we finalized for the CY 2017 VM in the CY 2015 PFS final rule with comment period for groups with 2 or more EPs and physician solo practitioners, with the exception discussed in section III.M.4.c. of this proposed rule that in CY 2018 we propose to apply both the upward and downward adjustments under the quality-tiering methodology to groups with 2 to 9 EPs and physician solo practitioners that are in Category 1.

For CY 2018, we propose to apply a −4.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs that fall in Category 2. In addition, we propose to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to −4.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as low quality/high cost and to set the adjustment to −2.0 percent for groups classified as either low quality/average cost or average quality/high cost. We also propose to set the maximum upward adjustment under the quality-tiering methodology in CY 2018 to +4.0x for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as high quality/low cost and to set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. Table 33 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These proposed payment amounts would be applicable to all of the physicians, NPs, PAs, CNSs, and CRNAs who bill under a group's TIN in CY 2018.

For CY 2018, we propose to apply a −2.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 2. In addition, we propose to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to −2.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners classified as low quality/high cost and to set the adjustment to −1.0 percent for groups and physciain solo practitioners classified as either low quality/average cost or average quality/high cost. We also propose to set the maximum upward adjustment under the quality-tiering methodology in CY 2018 to +2.0x for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners classified as high quality/low cost and to set the adjustment to +1.0x for groups and physician solo practitioners classified as either average quality/low cost or high quality/average cost. Table 34 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners. These proposed payment adjustment amounts would be applicable to all of the physicians, NPs, PAs, CNSs, and CRNAs who bill under a group's TIN and to physician solo practitioners in CY 2018.

For CY 2018, we propose to apply a −2.0 percent VM to PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs that fall in Category 2 for the CY 2018 VM. As proposed in section III.M.4.b. of this proposed rule, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We also propose that the maximum upward adjustment under the quality-tiering methodology in CY 2018 for PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs that fall in Category 1 would be +2.0x if a group or solo practitioner is classified as high quality/low cost and +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. As established in the CY 2015 PFS final rule with comment period (79 FR 67937), these groups and solo practitioners will be held harmless from any downward adjustments under the quality-tiering methodology in CY 2018, if classified as low quality/high cost, low quality/average cost, or average quality/high cost. Table 35 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners. These groups and solo practitioners will have had less time to become familiar with the QRURs since they will receive QRURs for the first time in the Fall of 2015; whereas, groups consisting of both physicians and nonphysician EPs and physician solo practitioners received QRURs in the Fall of 2014 or in previous years, which enable them to understand and improve performance on the measures used in the VM. We believe our proposed approach would reward groups and solo practitioners that provide high-quality/low-cost care. In addition, a smaller increase in the maximum amount of payment at risk would be consistent with our stated focus on gradual implementation of the VM.

We also propose to continue to provide an additional upward payment adjustment of +1.0x to groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology and have average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores. Lastly, we propose to revise § 414.1270, and § 414.1275(c)(4) and (d)(3) to reflect the proposed changes to the payment adjustments under the VM for the CY 2018 payment adjustment period. We seek comments on all of these proposals.

TABLE 33—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS 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 PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 34—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS WITH 2 TO 9 EPS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	−1.0%	+0.0%	*+1.0x
High cost	−2.0%	−1.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 35—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PAS, NPS, CNSS, AND CRNAS IN GROUPS CONSISTING OF NONPHYSICIAN EPS AND PAS, NPS, CNSS, AND CRNAS WHO ARE SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	+0.0%	+0.0%	*+1.0x
High cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners are eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), we note that the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for upward adjustments under the VM. Consequently, the upward payment adjustment factor (''x'' in Tables 33, 34, and 34) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

g. Finality of the VM Upward Payment Adjustment Factor

Beginning with the CY 2015 VM (77 FR 69324 through 69325), we established that the upward payment adjustment factor (''x'') would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We are also proposing a similar policy for the CY 2018 VM as discussed in section III.M.4.h. of this proposed rule. In the interest of providing EPs that are eligible for an upward payment adjustment under the VM with finality, and to minimize the cost of reprocessing claims, we propose that we would not recalculate the upward payment adjustment factor for an applicable payment adjustment period after the adjustment factor is made public, unless CMS determines that a significant error was made in the calculation of the adjustment factor. We seek public comment on this proposal.

h. Performance Period

In the CY 2014 PFS final rule with comment period (78 FR 74772), we adopted a policy that we will use performance on quality and cost measures during CY 2015 to calculate the VM that would apply to items and services for which payment is made under the PFS during CY 2017. Likewise, we propose to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. Accordingly, we propose to add § 414.1215(d) to indicate that the performance period is CY 2016 for VM adjustments made in the CY 2018 payment adjustment period. We seek comment on this proposal.

i. Quality Measures

In the CY 2015 PFS final rule with comment period (79 FR 67956), we aligned our policies for the VM for CY 2017 with the PQRS group reporting mechanisms available to groups in CY 2015 and the PQRS reporting mechanisms available to individual EPs in CY 2015, such that data that groups submit for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2015 and the data that individual EPs submit through any of the individual PQRS reporting mechanisms in CY 2015 will be used for calculating the quality composite under the quality-tiering approach for the VM for CY 2017. Moreover, we finalized the use of all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2017, to the extent that a group (or individual EPs in the group, in the case of the ''50 percent option'') or solo practitioner submits data on these measures (79 FR 67956). We also noted that, groups with two or more EPs can elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We finalized our policy to continue to include the three outcome measures in § 414.1230 in the quality measures used for the VM in CY 2017. These measures are: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

In § 414.1270(c)(4), we finalized that for groups that are assessed under the ''50 percent option'' for the CY 2017 VM, where all of the EPs in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS QCDR in CY 2015, and we are unable to receive quality performance data for those EPs, then we will classify the group's quality composite score as ''average'' under the quality-tiering methodology. Because this is the same policy as for the CY 2016 payment adjustment period, we also made a conforming revision to § 414.1270(b)(4) (79 FR 67956). Moreover, we finalized a policy that, for groups that are assessed under the ''50 percent option'' where some EPs in the group report data using a QCDR and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, then we will calculate the group's score based on the reported performance data that we obtain through those other PQRS reporting mechanisms. We finalized a policy that, beginning with the CY 2014 performance period, measures reported through a PQRS QCDR that are new to PQRS will not be included in the quality composite for the VM until such time as we have historical data to calculate benchmarks for them. Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure's performance rate during the year prior

to the performance period (79 FR 67956). We finalized a policy, beginning with the CY 2017 payment adjustment period, to increase the case minimum from 20 cases to 200 cases for the all-cause hospital readmissions measure as described in § 414.1230(c) to be included in the quality composite for the VM. We finalized that we will exclude the measure from the VM calculation for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period, and all remaining measures in the domain will be given equal weight. We codified this change in the case minimum at § 414.1265.

(1) PQRS Reporting Mechanisms

It is important to continue to align the VM for CY 2018 with the requirements of the PQRS, because quality reporting is a necessary component of quality improvement. We also seek to avoid placing an undue burden on EPs to report such data. Accordingly, for purposes of the VM for CY 2018, we propose to continue to include in the VM all of the PQRS GPRO reporting mechanisms available to groups for the PQRS reporting periods in CY 2016 and all of the PQRS reporting mechanisms available to individual EPs for the PQRS reporting periods in CY 2016. These reporting mechanisms are described in Tables 20 and 21 of this proposed rule.

(2) PQRS Quality Measures

We propose to continue to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2018 to the extent that a group (or individual EPs in the group, in the case of the ''50 percent option'') or solo practitioner submits data on these measures. These PQRS quality measures are described in Tables 22 through 30 of this proposed rule.

(3) Benchmarks for eCQMs

Currently, the VM program utilizes quality of care measure benchmarks for a given performance year that are calculated as the case-weighted mean of the prior year's performance rates, inclusive of all available PQRS reporting mechanisms for that measure (claims, registries, Electronic Health Record (EHR), or Web Interface (WI)). We finalized this policy in CY 2013 and stated we would consider the effects of our policy as we implemented the VM and that we may consider changes and refinements in the future (77 FR 69322).

From experience in utilizing PQRS measures in the VM, we have become aware that a given measure may be calculated differently when it is collected through an EHR, and are making a proposal to address this issue. We refer to quality measures collected through EHRs as ''eCQMs.'' We note several variances with eCQMs compared to equivalent measures reported via a different reporting mechanism. First, the inclusion of all-payer data for the eCQMs differentiates them sufficiently from their equivalent measures reported via the other PQRS reporting mechanisms, which utilize Medicare FFS data. The inclusion of all-payer data may increase the cohort size and incorporate a pool of beneficiaries with different characteristics than those captured with Medicare FFS data. As our goal is to focus on how groups of EPs or individual EPs' performance differs from the benchmark on a measure-by-measure basis, we recognize the need to utilize separate eCQM benchmarks that allow us to compare eCQM measure performance rates to a benchmark that better reflects the measures' specifications. Second, eCQMs follow a different annual update cycle than do other versions of measures, and consequently, they are not always consistent with the current version of a measure as it is reported via claims, registries, or Web Interface. For example, during a given performance period, an eCQM's specifications might require data collection on a different age range than the specifications of the same measure reported via other reporting mechanisms. This means that the eCQM version of a measure may differ from the specifications of the all-mechanism benchmark, to which it is currently compared. Because of these differences, we propose to change our benchmark policy to indicate that eCQMs, as identified by their CMS eMeasure IDs, which are distinct from the CMS/PQRS measure numbers for other reporting mechanisms, will be recognized as distinct measures under the VM. As such, we would exclude eCQM measures from the overall benchmark for a given measure and create separate eCQM benchmarks, based on the CMS eMeasure ID. We propose to make this change beginning with the CY 2016 performance period, for which the eCQM benchmarks would be calculated based on CY 2015 performance data.

We seek comment on this proposal.

(4) CAHPS Reporting

In our efforts to maintain alignment with the PQRS quality reporting requirements, we note that the criteria for administration of the CAHPS for PQRS survey for the CY 2016 performance period will contain 6 months of data as proposed in Section III.I.5.a of this proposed rule. We believe that the CAHPS for PQRS data administered during this 6-month period would be sufficiently reliable so that we could meaningfully include it in a group's quality composite score under the Value Modifier, should they elect to have CAHPS for PQRS included in their VM calculation. In order for us to use the data to calculate the score, we would require data for each summary survey measure on at least 20 beneficiaries which is the reliability standard for the value-based payment modifier (77 FR 69322–69323). We note that we took a similar approach in the CY 2014 PFS Final Rule (78 FR 74772) with regard to the 6-month reporting period for individual eligible professionals reporting via qualified registries under PQRS for the CY 2014 PQRS incentive and CY 2016 payment adjustment. Additionally, in the CY 2015 PFS Final Rule (79 FR 67956), we noted that groups with two or more EPs could elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We propose to continue this policy for the CY 2016 performance period for the CY 2018 VM.

(5) Quality Measures for the Shared Savings Program

In the CY 2015 PFS final rule with comment period (79 FR 67957), we finalized a policy to use the ACO GPRO Web Interface measures and the Shared Savings Program ACO all-cause readmission measure to calculate a quality composite score for groups and solo practitioners who participate in an ACO under the Shared Savings Program. Also, we finalized a policy to apply the benchmark for quality measures for the VM as described under § 414.1250 to determine the standardized score for quality measures for groups and solo practitioners participating in ACOs under the Shared Savings Program.

We believe patient surveys are important tools for assessing beneficiary experience of care and outcomes. Accordingly, we are proposing that starting with the CY 2018 payment adjustment period, the ACO CAHPS survey will be required as an additional component of the VM quality composite for TINs participating in the Shared Savings Program. CAHPS surveys for Shared Savings Program ACOs have been collected since 2013, for the 2012 reporting period. In the 2014 reporting period, we provided two versions of the CAHPS for ACOs survey to assess patient experience ACO–8 and ACO–12, with Shared Savings Program ACOs

having the option to use either survey. We note that under the VM CAHPS for PQRS is optional for groups that report it and these groups must elect to have their CAHPS performance used in their VM quality composite calculations. As both PQRS and Shared Savings Program ACOs report on CAHPS for their Medicare FFS populations, there is an overlap between the CAHPS survey data collected for both programs and we have calculated 2014 performance period prior year benchmarks on 11 of the 12 ACO CAHPS summary survey measures for the VM. We believe that by the CY 2016 performance period, we will have sufficient data and experience with calculating these survey measures in the VM, to require the ACO CAHPS measures in conjunction with the GPRO WI measures and the all-cause readmission measure in the calculation of a quality composite score for groups and solo practitioners participating in an ACO under Shared Savings Program. We propose to include the CAHPS for ACOs survey in the quality composite of the VM for TINs participating in ACOs in the Shared Savings Program, beginning with the CY 2016 performance period and the CY 2018 payment adjustment period. We propose that whichever version of the CAHPS for ACOs survey the ACO chooses to administer will be included in the TIN's quality composite for the VM. We propose to make corresponding changes to § 414.1210(b)(2)(i)(B). We seek comment on this proposal.

j. Expansion of the Informal Inquiry Process To Allow Corrections for the Value-Based Payment Modifier

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. We stated that we intend to disseminate reports containing CY 2013 data in Fall 2014 to groups of physicians subject to the VM in 2015 and that we will make a help desk available to address questions related to the reports, and we have since followed through on those actions.

In the CY 2015 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) finalized 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 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 providers 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 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 CMS or a third-party vendor made an error in the calculation of the quality composite. We propose to continue this policy for the CY 2017 payment adjustment and future adjustment periods or until such a time that the operational infrastructure is in place to allow the recomputation of data. We seek comment on this proposal.

Our overall approach to the VM is based on participation in the PQRS. Beginning with the CY 2016 payment adjustment period for the VM, groups of physicians (or individual EPs in the group, in the case of the 50 percent option) must meet the criteria to avoid the CY 2016 PQRS payment adjustment, to be classified as Category 1 for the VM and avoid an automatic downward adjustment under the VM. The payment adjustment for the VM is applied at the TIN level whereas the PQRS payment adjustment is applied at the TIN/NPI level. We believe that we need a policy to address the circumstance in which a group is initially determined not to have met the criteria to avoid the PQRS payment adjustment and subsequently, through the informal review process, at least 50 percent of its EPs are determined to have met the criteria to avoid the PQRS payment adjustment as individuals. We note that the informal review submission period will occur during the 60 days following release of the QRURs for the 2016 VM and subsequent years. We believe that this will allow us sufficient time to process the majority of the requests before finalizing the adjustment factor. We propose to 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 for satisfactory reporting of data on PQRS quality measures as individuals for the relevant CY PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the relevant CY PQRS payment adjustment. Moreover, we note that if the group was initially classified as Category 2, then we do not expect to have data for calculating their quality composite, in which case they'd be classified as ''average quality'', however, if the data is available in a timely manner, then we would recalculate the quality composite. We seek comments on this proposal.

k. Minimum Episode Count for the Medicare Spending Per Beneficiary (MSPB) Measure

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the MSPB measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. We finalized a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a TIN's cost composite. We stated that the nonspecialty-adjusted version of the measure using 2011 data had high reliability with a 20 episode minimum (79 FR 74779).

The reliability results presented in the CY 2014 PFS final rule with comment period (79 FR 74779), which supported the 20 episode case minimum, were based on the non-specialty-adjusted measure instead of the specialty-adjusted measure. We refined the methodology to account for the change in measure specifications and the results showed that the specialty-adjusted measure was more reliable at higher episode case minimums. Using a more appropriate methodology for calculating reliability, we have found that the specialty-adjusted measure does not have moderate or high reliability with a 20 episode minimum for many groups. Table 36 shows the reliability of the measure for different group sizes as the case minimum increases.

TABLE 36—SPECIALTY-ADJUSTED MSPB AMOUNT, PERCENT ABOVE 0.4 RELIABILITY THRESHOLD

Specialty-adjusted MSPB amount	All solo practitioners and groups	Solo practitioners	Groups with 2–9 EPs	Groups with 10–24 EPs	Groups with 25–99 EPs	Groups with 100+ EPs
Groups and Solo Practitioners with 20+ Episodes						
Percent above 0.4	40.1%	18.1%	41.7%	60.9%	66.5%	89.7%
Number of groups	29,190	10,639	10,505	3,664	3,229	1,153
Groups and Solo Practitioners with 50+ Episodes						
Percent above 0.4	80.2%	60.8%	79.0%	90.3%	91.6%	97.0%
Number of groups	15,881	3,406	6,194	2,699	2,499	1,083
Groups and Solo Practitioners with 60+ Episodes						
Percent above 0.4	86.8%	71.9%	84.6%	93.8%	94.7%	98.3%
Number of groups	13,614	2,416	5,279	2,506	2,352	1,061
Groups and Solo Practitioners with 75+ Episodes						
Percent above 0.4	92.9%	82.4%	91.1%	96.6%	97.3%	98.8%
Number of groups	11,213	1,567	4,182	2,256	2,173	1,035
Groups and Solo Practitioners with 100+ Episodes						
Percent above 0.4	97.6%	93.8%	96.3%	98.6%	99.2%	99.5%
Number of groups	8,543	785	2,873	1,924	1,957	1,004

Given that the measure has moderate reliability (above 0.4) for only 40.1 percent of all groups and solo practitioners and is as low as 18.1 percent for solo practitioners with an episode minimum of 20, we propose to increase the episode minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. Although this reduces the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite (from 29,190 to 8,543 based on 2013 data), we do not believe we should use the measure in calculating the cost composite if it is not reliable at the 20 episode minimum. We note that this change in policy could create a situation in which a group that would have performed well on this measure would no longer have this measure included in its cost composite, which could negatively impact their cost composite, and ultimately their VM adjustment. However, we believe that it would not be appropriate to include this measure in the cost composite even for those groups that performed well. Rather, we believe that it is more important to ensure that only reliable measures are included in the VM, and we want to avoid a situation in which groups or solo practitioners who may have performed poorly on the measure using a 20 episode minimum may receive a downward adjustment to payments under the VM as a result of a measure that was not reliable. We propose to add § 414.1265(a)(2) to reflect a case minimum of 100 episodes for the MSPB measure. We are seeking comment on this proposal.

We also considered increasing the episode minimum to 75 instead of 100. This would allow us to include the MSPB measure in the cost composite for a larger number of groups but we believe that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum. We welcome comment on this alternative we considered, as well as other potential minimum case thresholds for this measure.

We also considered revising the case minimum for the MSPB measure beginning with the CY 2016 payment adjustment period and CY 2014 performance period, but did not propose this policy, because this PFS rule will be finalized after the 2014 QRURs with the 2016 VM payment adjustment information are released. We note that, using an episode minimum of 20 for the 2016 VM, the MSPB measure has moderate reliability for majority of the groups that will be subject to the VM in 2016 (60.9 percent of groups with 10–24 EPs, 66.5 percent of groups with 25–99 EPs and 89.7 percent of groups with 100 or more EPs).

l. Inclusion of Maryland Hospital Stays in Definition of Index Admissions

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the MSPB

measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. We indicated in the 2014 proposed rule with comment period (78 FR 43494) that we would use the MSPB measure as specified for the Hospital Inpatient Quality Reporting (IQR) and Hospital Value Based Purchasing (VBP) Program with the exception of changes to the attribution methodology. The MSPB measure used for the Hospital IQR and Hospital VBP Programs does not include hospitalizations at Maryland hospitals as an index admission that would trigger an episode because Maryland hospitals are not paid under the Inpatient Prospective Payment System (IPPS) and do not participate in the Hospital VBP Program. The result is that groups and solo practitioners in Maryland would not have the MSPB measure included in their cost composite under the Value Modifier. We propose that, beginning with the 2018 VM, we change the definition of index admission used for the MSPB used in the VM program to include inpatient hospitalizations at Maryland hospitals. This change would allow CMS to include this measure in the calculation of the cost composite for groups and solo practitioners in Maryland, consistent with what is done for providers in others states. Under this proposal, we would continue to standardized all Medicare claims as described in the ''CMS Price Standardization'' document, which can be found in the ''Measure Methodology'' section at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*. The standardization methodology is currently used in the calculation of the MSPB measure and is continually being reviewed and updated to account payment policy changes and updates; any methodological changes made across years are documented in the Appendix of the ''CMS Price Standardization'' document. We are seeking comment on our proposal to, beginning with the 2018 VM, include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM program.

m. Average Quality and Average Cost Designations in Certain Circumstances

In the CY 2015 PFS final rule with comment period (79 FR 67934), we clarified a policy that was finalized at § 414.1270, that beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a cost composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure with at least 20 cases. We observed that groups that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries, and thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). We stated in the CY 2014 PFS final rule with comment period (78 FR 74780) that we believe this policy is reasonable because we would have insufficient information on which to classify the groups' costs as ''high'' or ''low'' under the quality-tiering methodology. Moreover, we believed that to the extent a group's quality composite is classified as high or low, the group's VM should reflect that classification. As discussed in section III.M.4.k. of this proposed rule, beginning with the CY 2017 payment adjustment period, we are proposing to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes. Therefore, we propose to revise § 414.1265(b) to indicate that a group or solo practitioner subject to the VM would receive a cost composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure that meets the minimum number of cases required for the measure to be included in the calculation of the cost composite, as required in § 414.1265. To improve the organization of the regulation text, we also propose to move the provisions at § 414.1270(b)(5) and (c)(5) to § 414.1265(b)(3).

The quality composite score calculated for each group and solo practitioner subject to the VM is based on the PQRS measures reported by the group or solo practitioner and three claims-based outcome measures, as described in § 414.1225 and § 414.1230, respectively. A quality measure must have 20 or more cases in order to be included in the calculation of the quality composite; however, beginning with the CY 2017 payment adjustment period, the all-cause hospital readmissions measure must have 200 or more cases in order to be included. Section 414.1265(a) describes the minimum number of cases required for the quality and cost measures to be included in the calculation of the quality and cost composites, respectively. We believe it is important to have a policy to determine the designation of the quality composite when a quality measure cannot be calculated reliably that is similar to the one established for the cost composite. Therefore, we propose that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a quality composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one quality measure that meets the minimum number of cases required for the measure to be included in the calculation of the quality composite, as required at § 414.1265. Consequently, to the extent a group or solo practitioner's cost composite is classified as high, average, or low, the group or solo practitioner's VM would reflect that classification. We propose to incorporate this proposal at § 414.1265(b)(2).

Current § 414.1265(b) states that in a performance period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the VM. In light of our proposals discussed in this section of the proposed rule, we do not believe this policy is necessary beginning with the CY 2016 payment adjustment period. As proposed above, the cost composite for a group or solo practitioner would be classified as average if there is not at least one cost measure that can be calculated reliably. Furthermore, we are proposing that the quality composite for a group or solo practitioner would be classified as average if there is not at least one quality measure that can be calculated reliably. Therefore, we propose to specify in § 414.1265(b)(1) that this policy was applicable only for the CY 2015 payment adjustment period.

n. Technical Changes to the ''Benchmarks for Cost Measures'' Section of Regulation Text

In the CY 2014 PFS final rule with comment period (78 FR 74781 to 74784), we finalized a policy to use the specialty adjustment method to create the standardized score for each group's cost measure beginning with the CY 2016 VM that refines the peer group methodology to account for specialty mix. We also amended § 414.1255 to include this policy in the cost composite methodology. We propose to move § 414.1255(b) and (c) (describing specialty adjustment of cost measures and benchmarks for cost measures) to § 414.1235(c)(4) and (5) (Cost measure adjustments) and revise the regulation text to align with the specialty adjustment methodology finalized in the CY 2014 PFS final rule with comment period. This is a technical change to the

regulation text only and will not impact how the cost measures will be specialty-adjusted beginning with the CY 2016 VM.

For the CY 2015 VM, the peer group for calculating the benchmarks for cost measures was all groups of physician to which beneficiaries are attributed and that are subject to the VM (for example, for CY 2015, the cost measures of groups with 100 or more EPs was compared to the cost measures of other groups of 100 or more EPs). About the specialty adjustment method, we stated in the CY 2014 PFS final rule (78 FR 74783) that this methodology creates one national benchmark for each cost measure against which all groups (regardless of size) would be assessed in creating the group's standardized score. We did not codify this policy in the regulation text in the CY 2014 PFS final rule with comment period. We also note that the benchmark for a cost measure includes the performance data for groups and solo practitioners that meet the minimum number of cases for that measure as described under § 414.1265(a). We believe this policy ensures that only the data for measures that are considered statistically reliable are included in the benchmarks, in addition to being included in the calculation of the cost composite. Therefore, we propose to codify at § 414.1255(b) that beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated for all groups and solo practitioners that meet the minimum number cases for that measure under § 414.1265(a). We note that we are not proposing any revisions to the specialty adjustment method finalized in the CY 2014 PFS final rule with comment period (78 FR 74781 through 74784).

o. Discussion of Stratification of Cost Measure Benchmarks by Beneficiary Risk Score

In response to our previously-finalized policies, stakeholders have suggested that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. Some of these commenters stated that groups that work exclusively in post-acute and long-term care settings would be unable to perform well on cost measures under the current methodology. Another commenter stated that beneficiaries who receive care at home typically have high HCC scores and higher costs. We appreciate the concerns raised by commenters and agree that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and are outside of the control of the provider. We continue to believe that our current methodology of using HCC scores that include adjustments for Medicare and Medicaid eligibility status in addition to diagnoses, and replacing the highest 1 percent of costs with the cost of the 99th percentile for the highest cost beneficiaries, help address these concerns. To address concerns regarding specialties that might routinely treat more complex and consequently more costly beneficiaries, we finalized in the CY 2013 PFS final rule with comment period that we would apply a specialty adjustment to all cost measures used in the VM (78 FR 74776). This enables groups' costs to be compared to similarly-comprised groups, based on specialty.

We note that high costs within the post-acute and long-term care settings present a unique opportunity for these providers to improve performance on cost and quality measures. Although we continue to encourage providers to report quality measures for patients in these settings and to use the information contained in their QRUR to improve and achieve high levels of performance, we stated in the CY 2015 PFS final rule with comment period (79 FR 67932) that we would continue to monitor these groups and solo practitioners' performance under the VM and continue to explore potential risk adjustment refinements. One option we are considering would be to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles. In this way, within a given grouping (for example, a quartile or decile), there remains an opportunity to gain efficiencies in care and lower costs, while beneficiary severity of illness and practice characteristics may be more fully recognized at a smaller, and likely less-heterogeneous, attributed beneficiary level. We are not making any proposals on this matter at this time. We are seeking feedback on this potential approach as well as other approaches..

5. Physician Feedback Program

a. CY 2014 Quality and Resource Use Reports (QRURs) Based on CY 2014 Data and Disseminated in CY 2015

In Fall 2015, we plan to expand the Physician Feedback Program by making QRURs, containing data on cost and quality performance during calendar year 2014, available to all solo practitioner EPs and groups of EPs of all sizes, as identified by TIN, including nonphysician EP solo practitioners and groups comprised of nonphysician EPs. We also plan to make the 2014 QRURs available to Shared Savings Program ACO participant TINs and groups that include one or more EPs who participated in a Pioneer ACO or the CPC Initiative. The reports will contain valuable information about a TIN's actual performance during CY 2014 on the quality and cost measures that will be used to calculate the CY 2016 VM. For physicians in groups of 10 or more, the 2014 QRURs will provide information on how a group's quality and cost performance will affect their Medicare payments in 2016 through the application of the VM based on performance in 2014.

The report will provide data on a group's or solo practitioner's performance on quality measures they report under the PQRS, as well as the three claims-based outcome measures calculated for the VM and described at § 414.1230. The 2014 QRUR will accommodate new PQRS reporting options, including QCDRs and CAHPS for PQRS. In addition, the reports will present data assessing a group practice's or solo practitioner's performance on cost measures and information about the services and procedures that contributed most to costs. The cost measures in the 2014 QRUR are payment-standardized and risk-adjusted and are also specialty-adjusted to reflect the mix of physician specialties in a TIN. For the 2014 QRURs, we will provide more detailed per capita cost of service breakdowns for all six cost measures. The reports also will contain additional supplementary information on the individual PQRS measures for EPs reporting PQRS measures as individuals; enhanced drill down tables; and a dashboard with key performance measures.

In response to stakeholder feedback to provide more timely and actionable information on outcomes and cost measures, we provided for the first time a mid-year report, the 2014 Mid-Year QRUR (MYQRUR) in Spring 2015. The 2014 MYQRUR was provided to physician solo practitioners and groups of physicians nationwide who billed for Medicare-covered services under a single TIN over the period of July 1, 2013 through June 30, 2014. We disseminated Mid-Year QRURs in the spring of each year to provide interim information about performance only on those cost and quality outcomes measures that we calculate directly from Medicare administrative claims, based

on the most recent 12 months of data that are available. The MYQRURs are for informational purposes and do not estimate performance for the calculation of the VM. Beginning in Spring 2016, we intend to expand the distribution of MYQRURs to nonphysician EPs, solo practitioners, and groups composed of nonphysician EPs.

We will continue to refine the QRURs based on stakeholder feedback, and we invite comment on which aspects of the QRURs reports have been most useful and how we can improve access to and actionability of performance reports.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A) of the Act requires CMS to develop an episode grouper and include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper organizes administrative claims data into episodes.

In Summer 2014, we distributed the Supplemental QRUR: Episodes of Care based on 2012 data to groups with 100 or more EPs. The 2012 Supplemental QRUR provided information on 20 episode subtypes and 6 clinical episode-based measures. In Fall 2015, we expect to provide the 2014 Supplemental QRURs to all groups and solo practitioners nationwide who billed for Medicare-covered services under a single TIN in 2014 and for whom we are able to calculate at least one episode measure. The supplemental QRURs are provided in addition to the Annual and Mid-Year QRURs. They provide information on performance on episode-based cost measures that are not included in the VM, in order to help groups and solo practitioners understand the cost of care they provide to beneficiaries and work toward the provision of more efficient care. The 2014 Supplemental QRURs will likely include the 6 episode-based measures included in the 2012 Supplemental QRURS in addition to other episode-based payment measures. We will continue to seek stakeholder input as we develop the episode framework.

Lastly, we would to direct readers to the Physician Compare proposals in this rule (section III.H.), which propose the addition of a green check mark to the profile page of the Physician Compare Web site for providers receiving an upward adjustment under the VM starting in CY 2018. CY 2018 is the first year the VM applies to not only all physicians, but also all nonphysician EPs as well. More information is available about Physician Compare on the CMS Web site at *http://www.medicare.gov/physiciancompare/search.html*.

N. Physician Self-Referral Updates

1. Background

a. Statutory and Regulatory History

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. Section 13624 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), entitled ''Application of Medicare Rules Limiting Certain Physician Referrals,'' added a new paragraph (s) to section 1903 of the Act, to extend aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

Several more recent statutory changes have also affected the physician self-referral law. Section 6001 of the Affordable Care Act amended section 1877 of the Act to impose additional requirements for physician-owned hospitals to qualify for the rural provider and hospital ownership exceptions. Section 6409 of the Affordable Care Act required the Secretary, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol (SRDP) that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral law.

This rulemaking follows a history of rulemakings related to the physician self-referral law. 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. After 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 **Federal Register** on January 4, 2001 (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 (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 **Federal Register** on September 5, 2007 (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 (72 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; and (3) expansion of the definition of ''entity.''

After passage of the Affordable Care Act, we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period (75 FR 73170) that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals in order to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

b. Purpose of This Proposed Rule

This rule would update the physician self-referral regulations to accommodate

delivery and payment system reform, to reduce burden, and to facilitate compliance. We have learned from stakeholder inquiries, review of relevant literature, and self-disclosures submitted to the SRDP that additional clarification of certain provisions of the physician self-referral law would be helpful. In addition to clarifying the regulations, we are also interested in expanding access to needed health care services. In keeping with these goals, the proposed rule expands the regulations to establish two new exceptions and clarifies certain regulatory terminology and requirements.

2. Recruitment and Retention (§ 411.357(e) and § 411.357(t))

In this proposed rule, we are proposing to establish new policies and revise certain existing policies regarding recruitment assistance and retention payments. Specifically, we are proposing a new exception for assistance to physicians to employ nonphysician practitioners. In addition, we are proposing to clarify for federally qualified health centers (FQHCs) and rural health clinics (RHCs) how to determine the geographic areas that they serve for purposes of the exception at § 411.357(e) and to change the language at § 411.357(e)(1)(iii) to ensure the consistency we intend for the ''volume or value'' standard found throughout the statute and our regulations. We are also proposing to lengthen the required record retention period at § 411.357(e)(4)(iv) from 5 years to 6 years to ensure consistency with the proposed exception at § 411.357(x) and other CMS record retention policies. For the exception for retention payments to physicians in underserved areas, we are proposing to clarify how parties should calculate the maximum amount for permissible retention payments. We describe these proposals in detail below.

a. Assistance To Employ a Nonphysician Practitioner

(1) Background

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified at § 411.357(e). The regulatory exception permits recruitment payments by FQHCs and RHCs on the same basis as those permitted by hospitals, but like the statute, limits the applicability of the exception to the recruitment of physicians. In Phase III, we responded to requests by commenters that we expand § 411.357(e) to cover the recruitment of nonphysician practitioners into a hospital's service area, including into an existing group practice (72 FR 51049). We declined to establish a new exception at that time. Further, we indicated that ''[r]ecruitment payments made by a hospital directly to a nonphysician practitioner would not implicate the physician self-referral law, unless the nonphysician practitioner serves as a conduit for physician referrals or is an immediate family member of a referring physician. Payments made by a hospital to subsidize a physician practice's costs of recruiting and employing nonphysician practitioners would create a compensation arrangement between the hospital and the physician practice for which no exception would apply'' (72 FR 51049).

Significant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections, have occurred since the publication of Phase III. A primary care workforce shortage has been a concern for years. (See Advisory Committee on Training in Primary Care Medicine and Dentistry, ''Coming Home: the Patient-Centered Medical-Dental Home in Primary Care Training,'' 7th annual report to the Secretary of the U.S. Department of Health and Human Services and to Congress, December 2008, *http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/Reports/seventhreport.pdf*.) The Affordable Care Act expanded access to health care coverage to those previously uninsured. As a result, the need for primary care providers (including nonphysician practitioners) has increased, particularly in remote and underserved areas. (See Ewing, Joshua, et al., ''Meeting the Primary Care Needs of Rural America: Examining the Role of Non-Physician Providers,'' National Conference of State Legislatures, The Rural Health Connection, April 2013, *http://www.ncsl.org/documents/health/RuralBrief313.pdf*.) The projected rise in the demand for primary care is due also to a growing and aging population, according to the Health Resources and Services Administration (HRSA). (See HHS, HRSA, National Center for Health Workforce Analysis, ''Projecting the Supply and Demand for Primary Care Practitioners Through 2020,'' November 2013, *http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/*.) HRSA found that ''the demand for primary care physicians will grow more rapidly than physician supply, resulting in a projected shortage of more than 20,000 full-time equivalent physicians.'' (Id.) Similarly, a study in the Annals of Family Medicine journal projected the country will need 52,000 more primary care physicians by 2025. (Peterson, Stephen M., et al, ''Projecting US Primary Care Physician Workforce Needs: 2010–2025,'' 29 10(6) Ann. Of Fam. Med. 503 (2012).) Nonphysician practitioners, the fastest growing segment of the primary care workforce (Schwartz, Mark D., ''Health Care Reform and the Primary Care Workforce Bottleneck,'' 27(4) J. Gen. Intern. Med. 469, 470 (2011)), may help to mitigate this shortage. Finally, new and evolving care delivery models, which feature an increased role for nonphysician practitioners (often as care coordination facilitators or in team-based care) have been shown to improve patient outcomes while reducing costs, both of which are important Department goals as we move further toward quality- and value-based purchasing of health care services in the Medicare program and the health care system as a whole.

(2) New Exception

In light of the changes in the health care delivery and payment systems since we last considered the issue of nonphysician practitioner recruitment assistance to physicians, using the authority granted to the Secretary in section 1877(b)(4) of the Act, we are proposing a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of a nonphysician practitioner. We believe that this exception is timely, will promote beneficiary access to care, and will remove barriers that could frustrate certain goals of the Affordable Care Act. When structured with the safeguards described below, we do not believe that arrangements for assistance to physicians to employ nonphysician practitioners pose a risk of program or patient abuse.

We propose to establish a new exception at § 411.357(x) to permit remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing a nonphysician practitioner in the geographic area served by the hospital, FQHC, or RHC providing the remuneration. Because the physician self-referral law applies to financial relationships between physicians and entities furnishing DHS, the proposed exception is not structured to apply to remuneration from a hospital, FQHC, or RHC to a group practice or other type of physician

practice (both of which qualify as a ''physician organization,'' as defined at § 411.351) . However, under our regulations at § 411.354(c), remuneration from an entity furnishing DHS to a physician organization would be deemed to be a direct compensation arrangement between each physician who stands in the shoes of the physician organization and the entity furnishing DHS. A ''deemed'' direct compensation arrangement must satisfy the requirements of an applicable exception if the physician makes referrals to the DHS entity and the DHS entity bills the Medicare program for DHS furnished as a result of the physician's referrals. The proposed exception would be available to protect a direct compensation arrangement between a hospital, FQHC, or RHC providing remuneration to an individual physician, as well as ''deemed'' direct compensation arrangements between a hospital, FQHC, or RHC and the physicians standing in the shoes of the physician organization to which the hospital, FQHC, or RHC provided the remuneration. Parties would also need to apply the rules regarding indirect compensation arrangements at § 411.354(c) to any chain of financial relationships that runs between the entity furnishing DHS and any physician who does not stand in the shoes of the physician organization in order to determine whether an indirect compensation arrangement exists. If an indirect compensation arrangement exists as a result of remuneration provided by the entity furnishing DHS, it must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

The proposed exception would apply only where the nonphysician practitioner is a *bona fide* employee of the physician receiving the remuneration from the hospital (or of the physician's practice) and the purpose of the employment is to provide primary care services to patients of the physician practice. We believe that employing a nonphysician practitioner (rather than merely contracting on an independent basis with a nonphysician practitioner) indicates a commitment by the physician to increase the availability of patient care services to his or her patients on an ongoing basis and, as such, is an important safeguard against program and patient abuse. However, we are soliciting comments regarding whether we should also permit remuneration to physicians to assist in attracting nonphysician practitioners to their medical practices in an independent contractor capacity, and, if so, what requirements we should include for such arrangements (for example, a requirement that the arrangement between the physician and the nonphysician practitioner have a minimum term, such as 1 year).

Because our goal in proposing the exception at § 411.357(x) is to promote the expansion of access to primary care services—which we consider to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services—we are proposing to define ''nonphysician practitioner,'' for purposes of this exception, to include only physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. We believe that these are the types of nonphysician practitioners that furnish ''primary care services.'' We note that the exception would not protect arrangements for assistance to a physician to employ a certified registered nurse anesthetist. We solicit comments regarding whether there is a compelling need to expand the scope of the proposed exception to additional types of nonphysician practitioners who furnish primary care services.

We are also proposing at § 411.357(x)(1)(vi) a requirement that the nonphysician practitioner provide only primary care services to patients of the physician's practice. As noted, we consider general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services to be ''primary care services.'' Thus, the exception would not protect arrangements for assistance to a physician to employ a nonphysician practitioner who furnishes specialty care services, such as cardiology or surgical services, to the physician practice's patients. We solicit comments regarding whether we should consider other, more, or fewer types of services to be ''primary care services'' for purposes of proposed § 411.357(x), whether there is a compelling need to expand the scope of the proposed exception to nonphysician practitioners who provide services that are not considered ''primary care services'' and, if so, safeguards that could be included in a final exception to ensure no risk of program or patient abuse. We are proposing two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the nonphysician practitioner: (1) At least 90 percent of the patient care services furnished by the nonphysician practitioner must be primary care services; or (2) substantially all of the patient care services furnished by the nonphysician practitioner must be primary care services. We would define ''substantially all'' patient care services consistent with our regulations; that is, at least 75 percent of the nonphysician practitioner's services to patients of the physician's practice must be primary care services. (See § 411.352(d) and § 411.356(c)(1).) We are soliciting comments regarding which of these alternatives is most appropriate and the nature of the documentation necessary to measure the nonphysician practitioner's services.

We do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their nonphysician practitioner employment and other practice costs. Therefore, we are proposing a cap on the amount of remuneration from the hospital to the physician and a requirement that the hospital may not provide assistance for a period longer than the first 2 consecutive years of the nonphysician practitioner's employment by the physician. Under proposed § 411.357(x)(1)(iii), the amount of remuneration from the hospital, FQHC, or RHC would be capped at the lower of: (1) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the nonphysician practitioner from the actual salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician. We propose to interpret ''benefits'' to include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the physician's practice. We believe that requiring a physician who receives assistance to employ a nonphysician practitioner to contribute to the costs of the nonphysician practitioner's salary and benefits would limit any windfall to the physician that could influence the physician's decision whether to refer patients to the hospital, FQHC, or RHC providing the assistance. Limiting the remuneration from the hospital, FQHC, or RHC to the ''actual'' amount paid to the nonphysician practitioner should ensure that the nonphysician practitioner is the true beneficiary of the arrangement between the physician the hospital, FQHC, or RHC providing the subsidy. We recognize that there may be income tax implications for the physician receiving the remuneration from the hospital, FQHC, or RHC. Because the proposed exception would protect only

remuneration to reimburse a physician for amounts actually paid to the nonphysician practitioner, the hospital, FQHC, or RHC providing the remuneration could not increase it to account for any tax implications to the physician. We seek comments regarding the cap on the amount of remuneration in the proposed exception, including whether the offset of receipts attributable to services furnished by the nonphysician practitioner should include all receipts for all services furnished by the nonphysician practitioner, regardless of payor and regardless of whether the services were primary care services. We also seek comments regarding whether we should structure the exception with additional or different safeguards to ensure that the remuneration from the hospital, FQHC, or RHC directly benefits the nonphysician practitioner and whether it is necessary to address the issue of the tax implications that could result from the use of the exception to provide remuneration to a physician to assist in the employment a nonphysician practitioner.

The proposed exception is intended to permit subsidies necessary to expand access to primary care services; however, we do not believe that hospitals, FQHCs, and RHCs should bear the full costs of employing nonphysician practitioners who work in private physician practices. The 2-year limit on the assistance is intended to prevent ongoing payment to the physician that could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC. We solicit comments specifically addressing the time limitations set forth in our proposal.

The proposed exception at § 411.357(x) closely tracks the structure and requirements of the exception for physician recruitment at § 411.357(e). Similar to the exception at § 411.357(e), the proposed exception for assistance to employ nonphysician practitioners would include requirements that reference hospitals, but would apply in the same manner to FQHCs and RHCs that wish to provide assistance to physicians to employ nonphysician practitioners.

We are proposing requirements to safeguard against program or patient abuse similar to the requirements found in most of our exceptions in § 411.357. Specifically, we propose that an arrangement covered by the exception must be set out in writing and signed by the hospital providing the remuneration, the physician receiving the remuneration, and the nonphysician practitioner. In addition, the arrangement may not be conditioned on the physician's or the nonphysician practitioner's referral of patients to the hospital providing the remuneration. Further, the proposed exception would require that the remuneration from the hospital is not determined (directly or indirectly) in a manner that takes into account the volume or value of any actual or anticipated referrals by the physician or the nonphysician practitioner (or any other physician or nonphysician practitioner in the physician's practice) or other business generated between the parties. We note that the definition of ''referral'' at § 411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician. For this reason, for purposes of the requirements of the new exception, we have proposed at § 411.357(x)(3) to define the term ''referral'' as it relates to nonphysician practitioners as a request by a nonphysician practitioner that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS, but not including any DHS personally performed or provided by the nonphysician practitioner. The definition of ''referral'' at proposed § 411.357(x)(3) is modeled closely on the definition of ''referral'' at § 411.351. We are also proposing that the arrangement may not violate the federal anti-kickback statute or any federal or state law or regulation governing billing or claims submission. Finally, we are proposing that records of the actual amount of remuneration provided to the physician (and to the nonphysician practitioner) be maintained for a period of at least 6 years and be made available to the Secretary upon request. We believe that a 6-year record retention requirement is appropriate. The 6-year period is in line with the requirements of other laws and regulations that protect against program or patient abuse as well as other CMS record retention requirements. We seek comment regarding whether these ''general'' safeguards are sufficient to protect against program or patient abuse resulting from arrangements to assist with nonphysician practitioner employment, or if additional safeguards are necessary.

We are also proposing requirements for the employment arrangement between the physician receiving remuneration and the nonphysician practitioner that the remuneration assists the physician to employ. Specifically, we are proposing to require that the nonphysician practitioner be a *bona fide* employee of the physician or the physician's practice. In addition, we are proposing that the aggregate salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner must be consistent with fair market value. We recognize that employment arrangements may change over time, for example, moving from full-time status to part-time status or changing a compensation methodology from hourly payments to a pre-determined flat, monthly salary. Because of the fair market value requirement and because we are proposing a limit on the amount that the hospital may provide to the physician, we do not believe that it is necessary to require that the nonphysician practitioner's salary, signing bonus, and benefits be set in advance. In addition, we are proposing a requirement that the physician may not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC, and we intend to interpret this provision in the same way that we interpret the requirement at § 411.357(e)(4)(vi) with respect to physician recruitment arrangements.

In addition, we are proposing to include requirements to prevent gaming by ''rotating'' or ''cycling'' nonphysician practitioners through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC, an abuse that would effectively shift the long-term costs of employing nonphysician practitioners to the hospital, FQHC, or RHC. We are also concerned that parties may misuse the exception to shift to a hospital, FQHC, or RHC the costs of a nonphysician practitioner who is currently employed by a physician but provides patient care services in a medical office of the physician that is located outside of the geographic area served by the hospital, FQHC, or RHC. To address these concerns, we are proposing that the hospital, FQHC, or RHC may not provide assistance to a physician to employ a nonphysician practitioner if: (1) the nonphysician practitioner has practiced in the geographic area served by the hospital, FQHC, or RHC within the 3 years prior to becoming employed by the physician; or (2) the nonphysician practitioner was employed or otherwise engaged by a physician with a medical office in the geographic area served by the hospital,

FQHC, or RHC within the 3 years prior to becoming employed by the physician, even if the nonphysician practitioner did not provide patient care services in that office. We believe that 3 years is a reasonable limit to protect the program and prevent abuse, but we solicit comments regarding the appropriateness of this timeframe. For consistency and to ease administrative burden, we propose to define ''geographic area served by the hospital'' to have the same meaning assigned to this term in the exception at § 411.357(e) for physician recruitment, and to define the term ''geographic area served'' by a FQHC or RHC to have the same meaning assigned to this term in proposed § 411.357(e)(6)(ii) described in this section II.N.2.b of this proposed rule.

Finally, we are soliciting comments regarding whether additional safeguards are necessary to protect against program or patient abuse that might result from arrangements that would be covered by proposed § 411.357(x). We are particularly interested in comments addressing whether we should limit the number of times a hospital, FQHC, or RHC may assist the same physician with the employment of nonphysician practitioners and, if so, during what time period that limitation should apply. For example, should we limit the use of the exception to no more than once every 3 years with respect to a particular physician or no more than three times in the aggregate (regardless of time period) with respect to a particular physician? Could this type of limitation potentially undermine the goal of increased access to primary care in the event the nonphysician practitioner(s) employed by the physician receiving the assistance from the hospital, FQHC, or RHC left such employment after only a short period of time or moved from the geographic area served by the hospital, FQHC, or RHC? We are also interested in comments addressing whether the exception should include a requirement that there be a documented, objective need for additional primary care services in the geographic area served by the hospital, FQHC, or RHC. We also solicit comments specifically from FQHCs and RHCs regarding whether this exception would be useful to such entities and any barriers to its use that they perceive.

b. Geographic Area Served by Federally Qualified Health Centers and Rural Health Clinics

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to an individual physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff. This exception was codified in our regulations at § 411.357(e) in the 1995 final rule. In Phase II, using our authority in section 1877(b)(4) of the Act, we expanded the exception to permit FQHCs to make recruitment payments to physicians on the same basis as hospitals (69 FR 16094 through 16095). Also in Phase II, we revised the exception to define the geographic area served by the hospital providing the recruitment remuneration as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients (69 FR 16094 through 16095). In Phase III, we made numerous amendments to the exception for physician recruitment, including permitting RHCs to utilize the exception in the same manner as hospitals and FQHCs (72 FR 51049). We also responded to commenters objecting to the Phase II definition of ''geographic area served by the hospital'' on the grounds that it ''hurts rural hospitals, and that it is very difficult for [FQHCs] to satisfy'' by revising the exception to permit a hospital located in a rural area to determine the geographic area served by the hospital using an alternative test that encompasses the lowest number of contiguous (or in some cases, noncontiguous) zip codes from which the hospital draws at least 90 percent of its inpatients (72 FR 51049 through 51050).

We intended for these definitions to apply to the recruitment of physicians by FQHCs and RHCs in the same manner as they apply to hospitals. However, the definitions of geographic area served by a hospital and rural hospital at § 411.357(e)(2)(i) and § 411.357(e)(2)(iii), respectively, are contingent on the volume of the hospital's inpatients. By definition, FQHCs and RHCs provide access to primary care services in rural areas or underserved areas and only treat patients as outpatients or ambulatory patients (CMS Pub. 100–02, Chap. 13, Sec. 10.1 and 10.2 (Rev. 201, Dec. 12, 2014)). Thus, although the regulatory exception for physician recruitment is available to FQHCs and RHCs, it provides no guidance as to the geographic area into which such an entity may recruit a physician, a concept critical for compliance with the exception's requirements. Therefore, we are proposing to revise § 411.357(e)(6) to add a new definition of the geographic area served by a FQHC or RHC. The purpose of this revision is to ensure that the definition of the geographic area served by FQHCs and RHCs appropriately captures the areas where their patients actually reside and to provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception at § 411.357(e).

We are proposing two alternative approaches for this policy, which aligns closely with the special optional rule for rural hospitals in § 411.357(e)(2)(iii) in recognition that rural hospitals, FQHCs, and RHCs often serve patients who are dispersed in wider geographic areas and may need to recruit physicians into more remote areas in order to achieve their goals of providing needed services to the communities that they serve. The first proposed approach would closely mirror our current definition of a rural hospital's geographic service area. It would indicate that the geographic area served by a FQHC or RHC is the area composed of the lowest number of contiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. If the FQHC or RHC draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the geographic area served by the FQHC or RHC may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of its patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the FQHC or RHC may include one or more zip codes from which it draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which it draws at least 90 percent of its patients.

In the alternative, we propose to define the geographic area served by a FQHC or RHC as the area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. This would be determined by beginning with the zip code in which the highest percentage of the FQHC's or RHC's patients reside, and continuing to add zip codes in decreasing order of percentage of patients. Although this approach would potentially result in larger geographic service areas than in the first approach, we see no potential for program or patient abuse in selecting noncontiguous zip codes to identify 90 percent of the patient base as long as there are patients in those areas. We seek comments on each of these alternatives, including whether patient

encounters is the appropriate measure for determining the geographic area served by a FQHC or RHC. Finally, we are soliciting comments specifically from FQHCs and RHCs regarding whether the exception at § 411.357(e) for physician recruitment is useful to such entities and any barriers to its use that they perceive.

c. Conforming Terminology: ''Takes into Account''

Under section 1877(e)(5) of the Act, the amount of remuneration cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of the recruited physician's referrals. Several other exceptions for compensation arrangements in section 1877(e) of the Act also contain provisions pertaining to the volume or value of a physician's referrals. In each case, the statutory language consistently states that compensation cannot be determined in a manner that ''takes into account'' the volume or value of a physician's referrals. (See sections 1877(e)(1)(A)(iv), (e)(1)(B)(iv), (e)(2)(B)(ii), (e)(3)(A)(v), (e)(3)(B)(i), (e)(5)(B), (e)(6)(A), and (e)(7)(A)(v).)

In Phase I, we developed a uniform interpretation of the volume or value standard that applies to all provisions under section 1877 of the Act and 42 CFR part 411, subpart J (66 FR 877). In Phase III, we revised the terminology at § 411.354(c)(2)(iii) pertaining to the volume or value of referrals in indirect compensation arrangements (72 FR 51027). The original language at § 411.354(c)(2)(iii) provided that an indirect compensation arrangement exists if the DHS entity has knowledge that a physician's aggregate compensation varies with, or otherwise reflects the volume or value of referrals. Phase III replaced the phrase ''otherwise reflects'' with ''takes into account.'' We explained that the phrases ''takes into account'' and ''otherwise reflects'' were not intended to have separate and different meanings, and that we were revising § 411.354(c)(2)(iii) for the sake of consistency (72 FR 51027). We made similar conforming changes to the regulations at § 411.354(c)(2)(ii), § 411.354 (c)(2)(iii), and § 411.354 (d)(1).

Despite the consistent use of the phrase ''takes into account'' in section 1877(e) of the Act and our uniform interpretation of the volume or value standard, not all the regulatory exceptions for compensation arrangements in § 411.357 use the phrase ''takes into account'' to describe the volume or value standard. In particular, the regulatory exception for the recruitment of physicians at § 411.357(e) has two provisions relating to the volume or value standard, and the provisions use different terms. Current § 411.357(e)(1)(iii) excepts payments to a recruited physician if the hospital does not determine the amount of compensation (directly or indirectly) ''based on'' the volume or value of referrals. Where the recruited physician joins a physician practice, § 411.357(e)(4)(v) provides that the amount of remuneration may not be determined in a manner that ''takes into account'' (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital. Like the physician recruitment exception, the following exceptions do not use the phrase ''takes into account'' in reference to the volume or value standard: the exception for medical staff incidental benefits at § 411.357(m); the exception for obstetrical malpractice insurance subsidies at § 411.357(r); and the exception for professional courtesy at § 411.357(s). The exception for obstetrical malpractice insurance premiums at § 411.357(r) provides that the amount of payment cannot be ''based on'' the volume or value of actual or anticipated referrals. The exceptions at § 411.357(m)(1) and § 411.357(s)(1) require that medical staff incidental benefits and professional courtesies, respectively, are offered to physicians ''without regard to'' the volume or value of referrals.

We are concerned that the use of different phrases pertaining to the volume or value of referrals (''takes into account,'' ''based on,'' and ''without regard to'') may cause some to conclude incorrectly that there are different volume or value standards in the compensation exceptions. We interpret the phrase ''takes into account'' throughout section 1877(e) of the Act as requiring that compensation not be determined in a manner that takes into account the volume or value of a physician's referrals. Nothing in the regulatory history of the exceptions for physician recruitment, medical staff incidental benefits, obstetrical malpractice insurance premiums, or professional courtesy arrangements suggests that the phrases ''based on'' and ''without regard to'' were intended to have a different meaning than ''takes into account.'' Rather, in Phase I we stated that we were adopting a uniform interpretation of the volume or value standard (66 FR 877), and in Phase III we revised our regulations to replace the phrases ''reflects'' and ''otherwise reflects'' with the phrase ''takes into account.'' Likewise, we do not believe that the ''takes into account'' standard for recruiting a physician who joins a physician practice (§ 411.357(e)(4)) differs in meaning from the current ''based on'' standard that otherwise applies to recruited physicians (§ 411.357(e)(1)(iii)). In sum, we believe that the there is no substantive difference between the phrases ''takes into account,'' ''based on,'' and ''without regard to,'' and that the terms have previously been used interchangeably in the compensation exceptions.

To clarify the regulations, we propose to modify § 411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, we propose to amend § 411.357(e) to require that the compensation provided to a recruited physician may not take into account (directly or indirectly) the volume or value of the recruited physician's referrals to the hospital, FQHC, or RHC providing the recruitment remuneration. We also propose to amend § 411.357(r) to require that the amount of payment under the arrangement not may take into account the volume or value of any actual or anticipated referrals. Lastly, we propose to revise the language of § 411.357(m) and § 411.357(s) to provide that the offer of medical staff incidental benefits or professional courtesy, respectively, may not take into account the volume or value of a physician's referrals. Taken together, these revisions would make the use of the phrase ''takes into account'' consistent throughout the compensation exceptions in § 411.357. The consistent terminology would reflect our longstanding policy that the volume or value standard in the various compensation exceptions should be interpreted uniformly.

d. Retention Payments in Underserved Areas

Our regulation at § 411.357(t) permits certain retention payments made to a physician with a practice located in an underserved area. This exception was first established in Phase II, and covered only retention payments made to a physician who has a bona fide firm, written recruitment offer that would require the physician to move his or her medical practice at least 25 miles and outside of the geographic area served by the hospital or FQHC making the retention payment (69 FR 16142). In Phase III, we modified the exception to permit a hospital, RHC, or FQHC to retain a physician who does not have a bona fide written offer of recruitment or

employment if the physician certifies in writing that he or she has a bona fide opportunity for future employment that meets the requirements at § 411.357(t)(2) (72 FR 51066).

In Phase III, we explained that a retention payment based on a physician certification may ''not exceed the lower of the following: (1) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician'' (72 FR 51066). We intended the regulations to mirror the preamble language precisely. However, the regulations at § 411.357(t)(2)(iv) state that such retention payments may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician. Thus, the current regulation text appears to permit entities to make retention payments that consider only part of the prior 24-month period instead of the entire period as we intended.

The policy stated in the Phase III preamble is correct and remains our policy at this time. Therefore, in order to avoid confusion due to potentially conflicting regulation text, we propose to modify our regulations at § 411.357(t)(2)(iv)(A) to reflect the regulatory intent we articulated in Phase III.

3. Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and Other Regulations

The SRDP enables providers and suppliers to disclose actual or potential violations of the physician self-referral law to CMS and authorizes the Secretary to reduce the amount potentially due and owing for disclosed violations. Since the SRDP was established, we have received numerous submissions to the SRDP disclosing actual or potential violations relating to the writing requirements of various compensation exceptions (for example, failure to set an arrangement out in writing, failure to obtain the signatures of the parties in a timely fashion, or failure to renew an arrangement that expired on its own terms after at least 1 year). This proposed rule would clarify the writing requirements of various compensation exceptions by making the terminology in the compensation exceptions more consistent and by providing policy guidance on the writing and 1-year minimum term requirement in many exceptions. In addition, to reduce the regulatory burden, we propose to except certain holdover arrangements, provided certain safeguards are met.

a. Writing Requirements in Certain Compensation Exceptions and Other Regulatory Provisions

The exceptions for the rental of office space and the rental of equipment (section 1877(e)(1) of the Act; § 411.357(a) and § 411.357(b)) require that a lease be set out in writing. Several other compensation exceptions have similar writing requirements: the exception at § 411.357(d) for personal service arrangements; the exception at § 411.357(e) for physician recruitment; the exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(l) for fair market value compensation; the exception at § 411.357(p) for indirect compensation arrangements; the exception at § 411.357(r) for obstetrical malpractice insurance subsidies; the exception at § 411.357(t) for retention payments in underserved areas; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Through our experience administering the SRDP, we have learned that there is uncertainty in the provider community regarding the writing requirement of the leasing and other compensation exceptions. In particular, we have been asked whether an arrangement must be reduced to a single ''formal'' written contract (that is, a single document that includes all material aspects of the arrangement) in order to satisfy the writing requirement of the applicable exception.

The original exception for the rental of office space required ''a written agreement, signed by the parties, for the rental or lease of the space . . ..'' (Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–386 section 6204(e)(1)). In OBRA 1993, the Congress clarified the exception for the rental of office space (H. Rept. 103–213 at 812). Section 13562(e)(1) of OBRA 1993 (codified at section 1877(e)(1) of the Act) provides exceptions for the rental of office space and equipment if ''the lease is set out in writing . . ..'' OBRA 1993 also excepted personal service arrangements if ''the arrangement is set out in writing . . ..'' (OBRA 1993 § 13562(e)(3), codified at section 1877(e)(3) of the Act). The current regulatory exceptions for the rental of office space and the rental of equipment require at § 411.357(a)(1) and § 411.357 (b)(1), respectively, that an ''agreement'' be set out in writing. In contrast, the regulatory exception for personal service arrangements requires at § 411.357(d)(1)(i) that the ''arrangement'' be set out in writing.

Despite the different terminology in the statutory and regulatory exceptions, we believe that the writing requirement for the leasing exceptions and the personal service arrangements exception is the same. Specifically, we interpret the term ''lease'' in sections 1877(e)(1)(A) and (B) of the Act to refer to the lease arrangement. Notably, in the statutory scheme of section 1877 of the Act, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements are classified as ''Exceptions Relating to Other Compensation Arrangements.'' The lease arrangement is the underlying financial relationship between the parties (that is, payments for the use of office space or equipment for a period of time). To satisfy the writing requirement, the facts and circumstances of the lease arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception. (See Phase II (69 FR 16110) for a similar discussion regarding arrangements among components of an academic medical center.)

In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.

Through the SRDP, we have learned that some stakeholders interpret the term ''agreement,'' as it is used in § 411.357(a)(1) and § 411.357 (b)(1), to mean that a single written contract is necessary to satisfy the writing requirement of the applicable exception. To clarify the exceptions for the rental

of office space and the rental of equipment, we propose to substitute the term ''lease arrangement'' for the term ''agreement'' in § 411.357(a)(1) and § 411.357(b)(1). We believe that this revision underscores the fact that the writing requirement at § 411.357(a)(1) and § 411.357(b)(1) for the rental of office space and the rental of equipment, respectively, is identical to the writing requirement at § 411.357(d)(1)(i) for personal service arrangements. Broadly speaking, we believe that there is no substantive difference among the writing requirements of the various compensation exceptions that require a writing. To emphasize the uniformity of the writing requirement in the compensation exceptions, we propose to remove the term ''agreement'' from the exception for physician recruitment at § 411.357(e)(4)(i), the exception for fair market value compensation at § 411.357(l)(1), the special rule on compensation that is set in advance at § 411.354(d)(1), and the special rule on physician referrals to a particular provider, practitioner, or supplier at § 411.354(d)(4)(i). To be clear, the revised rules would still require a writing. For instance, to satisfy the revised rule at § 411.354(d)(1) on compensation that is set in advance, the rate of compensation must be documented in writing before the services are performed. By removing the term ''agreement,'' we are simply clarifying that the rules do not require a particular kind of writing, for example, a formal contract.

In light of our proposal to clarify the writing requirement at § 411.354(d)(1), § 411.354(d)(4)(i), § 411.357(a)(1), § 411.357(b)(1), § 411.357(e)(4)(i), and § 411.357(1)(1) by removing the term ''agreement,'' we propose to make conforming changes where possible to other provisions in the compensation exceptions and the special rules on compensation. Specifically, we propose to replace the term ''agreement'' with the term ''lease arrangement'' in § 411.357(a)(2), § 411.357(a)(4), § 411.357(a)(5), § 411.357(a)(6), § 411.357(b)(3), § 411.357(b)(4), and § 411.357(b)(5). We propose to replace the term ''agreement'' with the term ''arrangement'' in § 411.357(c)(3) (exception for bona fide employment relationships) and § 411.357(f)(2) (exception for isolated transactions). Likewise, we propose to remove the phrase ''set forth in an agreement'' from the introductory language to the exception for fair market value compensation at § 411.357(l). Finally, we are also concerned that the words ''contract'' and ''contracted for,'' like the word ''agreement,'' may suggest that a formal contract or other specific kind of writing is required to satisfy the applicable exception. To address this issue, we propose to revise § 411.354(d)(4) by replacing the word ''contract'' as it relates to personal service arrangements with the word ''arrangement,'' and we propose similar changes to § 411.357(e)(1)(iv) and § 411.357(r)(2)(v), both of which refer back to § 411.354(d)(4). We propose to replace the phrase ''contracted for'' at § 411.357(d)(1)(iii) with the phrase ''covered by the arrangement.'' In the exception at § 411.357(p)(2) for indirect compensation arrangements, we propose to replace the phrase ''written contract'' with the word ''writing.''

Certain compensation exceptions use the phrase ''written agreement'': the exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Although these exceptions use the term ''written agreement,'' we are not proposing any revisions. The exception at § 411.357(h) is rarely used, because it only protects arrangements that began before, and continued without interruption since, December 19, 1989. The exceptions at § 411.357(v) and § 411.357(w) are aligned with the federal anti-kickback statute safe harbors at § 1001.952(x) and § 1001.952 (y) that protect the provision of these items and services. To avoid creating apparent inconsistencies between the physician self-referral law exceptions and the corresponding anti-kickback statute safe harbors, we are not modifying § 411.357(v) or § 411.357(w). However, we believe that the principles elucidated above regarding the writing requirements of the other compensation exceptions to the physician self-referral law also apply to § 411.357(v) and § 411.357(w).

b. Term Requirements in Certain Compensation Arrangements Exceptions

The exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) for the rental of office space, the rental of equipment, and personal service arrangements, respectively, require that the compensation arrangement between an entity furnishing DHS and a referring physician has a term of at least 1 year. Parties submitting self-disclosures to the SRDP have asked whether the term of the arrangement must be in writing to satisfy the requirements of the relevant exceptions. We propose to revise § 411.357(a)(2), § 411.357(b)(3), and § 411.357(d)(1)(iv) to clarify the documentation requirements related to the term of lease arrangements for the rental of office space, lease arrangements for the rental of equipment, and personal service arrangements.

The statutory exceptions for the rental of office space and the rental of equipment in sections 1877(e)(1)(A)(iii) and (B)(iii) of the Act require that the lease provides for a term of rental or lease for at least 1 year. The statutory exception for personal service arrangements in section 1877(e)(3)(A)(iv) of the Act requires that the term of the arrangement is at least 1 year. Although our regulations at § 411.357(d)(1)(iv) (the exception for personal service arrangements) use language similar to the statutory exception for personal service arrangements, our current regulations at § 411.357(a)(2) and § 411.357(b)(3) (the exceptions for the rental of office space and equipment, respectively) use the term ''agreement'' in addressing the minimum term requirement. As explained elsewhere in this proposed rule, we interpret ''lease'' in section 1877(e)(1) of the Act to refer to the lease arrangement between the parties, and we also believe that the writing requirement of sections 1877(e)(1)(A) and (B) of the Act is identical to the requirement in section 1877(e)(3) of the Act.

We believe that some stakeholders have interpreted the term ''agreement'' in § 411.357(a)(2) and § 411.357(b)(3) to mean that a formal written contract or other document with an explicit provision identifying the term of the arrangement is necessary to satisfy the 1-year term requirement of the exceptions. As we noted in the 1998 proposed rule, the 1-year term requirement is satisfied ''as long as the arrangement clearly establishes a business relationship that will last for at least 1 year'' (63 FR 1713). An arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement. Parties must have contemporaneous writings establishing that the arrangement lasted for at least 1 year, or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment, or services during the first year, as required by § 411.357(a)(2), § 411.357(b)(3), and § 411.357(d)(1)(iv), as applicable. Depending on the facts and circumstances of the arrangement and the available documentation, we believe that, as is the case with the writing requirement in these and other

exceptions, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, can establish that the arrangement in fact lasted for the required period of time. A formal contract or other document with an explicit ''term'' provision is generally not necessary to satisfy this element of the exception. To clarify that a written contract with a formalized ''term'' provision is not necessary to satisfy the regulations at § 411.357(a)(2) and § 411.357(b)(3), we propose to remove the word ''agreement'' and to revise the first sentence of these provisions to mirror the 1-year term requirement in the personal service arrangements exception at § 411.357(d)(1)(iv).

c. Holdover Arrangements

The exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) currently permit a ''holdover'' arrangement for up to 6 months if an arrangement of at least 1 year expires, the arrangement satisfies the requirements of the exception when it expires, and the arrangement continues on the same terms and conditions after its stated expiration. We propose to amend the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii) to permit indefinite holdovers, provided that certain additional safeguards are met. In the alternative, we propose to extend the holdover to a definite period that is greater than 6 months (for example, 1 year, 2 years, or 3 years), provided that additional safeguards are met. Finally, we propose to revise the exception for fair market value compensation at § 411.357(l)(2) to permit renewals of arrangements of any length of time, including arrangements for 1 year or greater.

The holdover provisions in § 411.357(a), § 411.357(b), and § 411.357(d) developed over the course of our rulemaking in response to inquiries regarding the expiration, termination, and renewal of arrangements. In the 1998 proposed rule, we stated that month-to-month arrangements after an arrangement of at least 1 year expired would not satisfy the 1-year requirement in the applicable exceptions (63 FR 1713). We explained that the purpose of the 1-year requirement is to except ''stable arrangements that cannot be renegotiated frequently to reflect the current volume or value of a physician's referrals.'' Because we were concerned that month-to-month arrangements could be frequently renegotiated, we required parties to renew arrangements (after the original arrangement of at least 1 year expired) in at least 1-year increments.

In Phase II, we addressed criticism of our statements in the 1998 proposed rule regarding month-to-month arrangements following the expiration of an arrangement that lasted at least 1 year, as required under the exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) (69 FR 16085 through 16086). One commenter suggested that there was little additional risk of program or patient abuse if a holdover rental continued on the same terms as the original lease arrangement. We agreed that there was little risk if a month-to-month holdover continued on the same terms and conditions as the original lease arrangement, but stated that our position related only to time-limited holdovers (that is, no more than 6 months) (69 FR 10685 through 10686). Thus, in Phase II we established the 6-month holdover provisions at § 411.357(a)(7) and § 411.357(b)(6) for lease arrangements. In Phase III, we declined to except an indefinite holdover for rental arrangements where a lessor is taking steps to remove a lessee, stating that 6 months is sufficient in the circumstances described by the commenter, which related to the lessee's refusal to vacate office space upon the expiration of a lease arrangement (72 FR 51045). Phase III also established at § 411.357(d)(vii) a 6-month holdover for personal service arrangements.

Through our administration of the SRDP, we have reviewed numerous rental and personal service arrangements that failed to satisfy the requirements of an applicable exception solely because the arrangement expired by its terms and the parties continued the arrangement on the same (compliant) terms and conditions after the 6-month holdover period ended. In our experience, an arrangement that continues beyond the 6-month period does not pose a risk of program or patient abuse, provided that the arrangement continues to satisfy the specific requirements of the applicable exception, including the requirements related to fair market value, compensation that does not take into account the volume or value of referrals or other business generated between the parties, and reasonableness of the arrangement. We have reconsidered our previous position and are proposing to eliminate the time limitations on holdovers with safeguards to address two potential sources of program or patient abuse: frequent renegotiation of short term arrangements based on a physician's referrals, and compensation or rental changes that become inconsistent with fair market value over time.

To prevent frequent renegotiation of short term arrangements, the holdover must continue on the same terms and conditions as the original arrangement. If the parties change the original terms and conditions of the arrangement during the holdover, we would consider this a new arrangement. The new arrangement would be subject to the 1-year term requirement at § 411.357(a)(2), § 411.357(b)(3), or § 411.357(d)(1)(iv) (or it must satisfy the requirements of the exception for fair market value compensation at § 411.357(l), if applicable). Specifically, the new arrangement must have a term of at least 1 year, and if the parties terminate the new arrangement with or without cause before the end of that year, they cannot enter into another arrangement for the same or similar space, equipment, or services until the expiration of the year. We believe that these safeguards, which are already incorporated into the current exceptions, prevent frequent renegotiations of short-term arrangements.

To ensure that compensation is consistent with or does not exceed fair market value, as applicable, the proposed holdover provisions require that the holdover arrangement satisfy all the elements of the applicable exception when the arrangement expires and on an ongoing basis during the holdover. Thus, if office space rental payments are fair market value when the lease arrangement expires, but the rental amount falls below fair market value at some point during the holdover, the lease arrangement would fail to satisfy the requirements of the applicable exception at § 411.357(a) as soon as the fair market value requirement is no longer satisfied, and DHS referrals by the physicians to the entity that is party to the arrangement would no longer be permissible. In addition, the entity could not bill the Medicare program for DHS furnished as a result of a referral made by the physician after the rental charges were no longer consistent with fair market value. The requirement that the arrangement is set out in writing continues to apply during the holdover. To satisfy this requirement, the parties must have documentary evidence that the arrangement in fact continued on the same terms and conditions. Depending on the facts and circumstances of the arrangement and the available documentation, the expired written agreement and a collection of documents, including contemporaneous documents evidencing the course of conduct

between the parties may satisfy the writing requirement for the holdover.

As noted above, we propose to revise the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii) to permit indefinite holdovers under certain conditions. Specifically, the arrangement must comply with the applicable exception when it expires by its own terms; the holdover must be on the same terms and conditions as the immediately preceding arrangement; and the holdover must continue to satisfy the requirements of the applicable exception. In the alternative, we propose to extend the holdover for a definite period (for example, a 1-, 2-, or 3-year holdover period) or for a period of time equivalent to the term of the immediately preceding arrangement (for example, a 2-year lease would be considered renewed for a new 2-year period). We believe that, if the holdover is extended for a definite period beyond 6 months, the safeguards outlined above for indefinite holdovers are necessary to prevent program or patient abuse. We are seeking comments on what additional safeguards, if any, are necessary to ensure that holdovers lasting longer than 6 months do not pose a risk of program or patient abuse.

In addition to our proposals to extend the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii), we propose to amend the exception at § 411.357(l) for fair market value compensation arrangements. Section 411.357(l)(2) currently allows arrangements for less than 1 year to be renewed any number of times, provided that the terms of the arrangement and the compensation for the same items or services do not change. We propose to amend § 411.357(l)(2) to permit arrangements of any timeframe, including arrangements for more than 1 year, to be renewed any number of times. We believe that the proposal does not pose a risk of patient or program abuse, because the arrangement must be renewed on the same terms and conditions, and the renewed arrangement must satisfy all the requirements of the exception at the time the physician makes a referral for DHS and the entity bills Medicare for the DHS. We seek comments as to whether the proposed revision of § 411.357(l)(2) would be necessary if we revise § 411.357(d)(1)(vii) to permit indefinite holdovers.

4. Definitions

In this proposed rule, we are proposing to revise several definitions in our regulations to improve clarity and ensure proper application of our policies. We describe below our specific proposals.

a. Remuneration (§ 411.351)

A compensation arrangement between a physician (or an immediate family member of such physician) and a DHS entity implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term ''compensation arrangement'' as any arrangement involving any ''remuneration'' between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following items, devices, or supplies does not create a compensation arrangement between the parties: Items, devices, or supplies that are ''used solely'' to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our regulations at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

We are concerned that the phrase ''used solely'' may misleadingly suggest that the provision of an item, device, or supply that can be used for two or more of the six purposes listed in section 1877(h)(C)(ii) of the Act constitutes remuneration between the parties giving rise to a compensation arrangement. In contrast, in the 1998 proposed rule, we interpreted the phrase ''solely'' to mean that the items must be used solely for the ''purposes listed in the statute'' (63 FR 1693). Importantly, the word ''purposes'' is used in the plural, and we did not state that an item must be used for only one purpose listed in the statute. We continue to believe that the phrase ''used solely'' means that an item, device, or supply cannot be used for any purpose other than the six purposes listed in the statute. Thus, if an item is used for two or more purposes listed in the statute, and it is not used for any other purpose (that is, any purpose not listed in the statute), then provision of the item does not constitute remuneration between the parties. We propose to revise the definition of ''remuneration'' at § 411.351 to make it clear that the item must be used solely for one or more of the six purposes listed in the statute.

Although we are not proposing regulatory revisions at this time, we are also concerned about potential confusion, especially for hospitals located in states included in the United States Court of Appeals for the Third Circuit, regarding whether remuneration is conferred by a hospital to a physician when both facility and professional services are provided to patients in a hospital-based department. Following commentary by the Third Circuit Court of Appeals in its decision in *United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009), we received an advisory opinion request and several self-disclosures submitted to the SRDP asking whether certain so-called ''split bill'' arrangements between physicians and DHS entities involve remuneration between the parties that gives rise to a compensation arrangement for purposes of the physician self-referral law. We are taking the opportunity afforded by this rulemaking to address this issue.

In *Kosenske*, the Third Circuit Court of Appeals held that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients constitutes remuneration under the physician self-referral law, even when the hospital bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only. We do not believe that such an arrangement involves remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another. Rather, the physician provides services to the patient and bills the payor for his or her services, and the DHS entity provides its resources and services to the patient and bills the payor for the resources and services. There is no remuneration between the parties for purposes of section 1877 of the Act.

In contrast, if a physician or a DHS entity bills a non-Medicare payor (that is, a commercial payor or self-pay patient) globally for both the physician's services and the hospital's resources and services, a benefit is conferred on the party receiving payment. Specifically, the party that bills globally receives payment for items or services provided by the other party. Such a global billing arrangement involves remuneration between the parties that implicates the physician self-referral law.

b. Compensation Arrangements –''Stand in the Shoes'' (§ 411.354(c))

Phase III included provisions under which all physicians would be treated as ''standing in the shoes'' of their physician organizations for purposes of applying the rules regarding direct and indirect compensation arrangements at § 411.354(c) (72 FR 51026 through 51030). (Since Phase II, we have considered a referring physician and the professional corporation of which he or she is the sole owner to be the same for purposes of the physician self-referral regulations (69 FR 16131).) The FY 2009 IPPS final rule amended § 411.354(c) to: (1) Treat a physician with an ownership or investment interest in a physician organization as standing in the shoes of that physician organization; and (2) permit parties to treat a physician who does not have an ownership or investment interest in a physician organization as standing in the shoes of that physician organization. An exception to the mandatory treatment of physicians with ownership or investment interests as standing in the shoes of their physician organizations was made for physicians with ''titular'' ownership or investment interests only (73 FR 48691 through 48700). A ''physician organization'' is defined at § 411.351 as a physician, a physician practice, or a group practice that complies with the requirements of § 411.352. Therefore, as of October 1, 2008, for purposes of determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician makes referrals for the furnishing of DHS, if the physician has an ownership or investment interest in the physician organization that is not merely titular, the physician stands in the shoes of the physician organization. The physician is considered to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes he or she stands.

In Phase III, we established the rule at § 411.354(c)(3)(i), which provides that a physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. The regulation also states that, when applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated ''between the parties'' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians). Our intent for this provision was to make clear that, under the Phase III ''stand in the shoes'' policy (which considered all physicians in a physician organization to stand in the shoes of the physician organization), each physician in the physician organization was considered a ''party'' to an arrangement between the physician organization and a DHS entity.

Following the FY 2009 IPPS final rule changes limiting the ''stand in the shoes'' rules only to physicians with ownership or investment interests in their physician organizations (other than those with merely a titular ownership or investment interests) and physicians who voluntarily stand in the shoes of their physician organizations, stakeholders inquired whether the change in the ''stand in the shoes'' policy meant that, when applying the exceptions in § 411.355 and § 411.357, for purposes of determining whether compensation takes into account the volume or value of referrals or other business generated between the ''parties,'' the only ''parties'' to consider are the physicians with ownership or investment interests in their physician organizations. This was not our intent in revising the ''stand in the shoes'' rules in the FY 2009 IPPS final rule.

To address the issue raised by the stakeholders, we are proposing to revise § 411.354(c)(3)(i) so that it is consistent with our work in the FY 2009 IPPS final rule. Our intent there was, and currently remains, that only physicians who stand in the shoes of their physician organization are considered parties to an arrangement for purposes of the signature requirements of the exceptions. For such purposes, we do not consider employees and independent contractors to be parties to a physician organization's arrangements unless they voluntarily stand in the shoes of the physician organization as permitted under § 411.354(c)(1)(iii) or § 411.354(c)(2)(iv)(B). Guidance regarding physicians who stand in the shoes of their physician organizations may be found on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html*. Specifically, consistent with our response in Frequently Asked Question #12318, for purposes of satisfying the requirements of an exception to the physician self-referral prohibition, we consider a physician who is standing in the shoes of his or physician organization to have satisfied the signature requirement of an applicable exception when the authorized signatory of the physician organization has signed the writing evidencing the arrangement.

For purposes other than satisfying the signature requirements of the exceptions, we remain concerned about the referrals of *all* physicians who are part of a physician organization that has a compensation arrangement with a DHS entity when we analyze whether the compensation between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated between the parties. If we did not consider the referrals of all the physicians in the physician organization, and instead only considered the referrals of those physicians who stand in the shoes of the physician organization, DHS entities would be permitted to establish compensation methodologies that take into account the volume or value referrals or other business generated by non-owner physicians in a physician organization when entering into a compensation arrangement with the physician organization. Therefore, our proposal would amend § 411.354(c)(3)(i) to clarify that, for all purposes other than the signature requirements, all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.

c. *Locum Tenens* Physician (§ 411.351)

The term ''*locum tenens* physician'' was first defined for purposes of the physician self-referral law in Phase I (66 FR 954). This definition is important because a *locum tenens* physician is considered a member of a group practice, and therefore the definition is relevant to whether a physician practice complies with the group practice requirements at § 411.352. In the Phase I preamble, we likened a *locum tenens* physician to one who is ''standing in the shoes'' of a regular physician, subject to certain requirements in CMS manual guidance (66 FR 900). Our regulations at § 411.351 have continuously defined a *locum tenens* physician as a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a physician, first within the definition of ''member of a group'' (66 FR 954) and later as a stand-alone defined term applicable to both group practices and other physicians (69 FR 16129). We note that the Phase I definition referenced the ''regular physician'' (66 FR 954).

As described in this section, in subsequent rulemaking, we established certain rules regarding when a physician ''stands in the shoes'' of his

or her physician organization. The ''stand in the shoes'' rules affect whether an arrangement may be analyzed as a direct or indirect compensation arrangement (See 72 FR 51027 through 51030, and 73 FR 48693 through 48700). The ''stand in the shoes'' provisions are specific to compensation arrangements and described in our regulations at § 411.354(c).

We propose to revise the definition of *locum tenens* physician to remove the reference to ''stand in the shoes.'' We believe that the definition of a *locum tenens* physician is clear without the phrase ''stands in the shoes.'' We also believe that it is clear that the ''stand in the shoes'' provisions specific to compensation arrangements are separate and distinct from the definition of a *locum tenens* physician. However, to eliminate unnecessary verbiage and to avoid any potential ambiguity, we propose to revise the definition of *locum tenens* physician at § 411.351 by removing the phrase ''stands in the shoes.''

5. Exception for Ownership of Publicly Traded Securities

Section 1877(c)(1) of the Act sets forth an exception for ownership in certain publicly traded securities and mutual funds. To qualify for the exception, securities must be:

- Investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public;
- Securities that are: (1) Listed on the New York Stock Exchange (NYSE), the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis; (2) foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or (3) traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD); and
- In a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

This exception is codified in our regulations at § 411.356(a), which closely mirrors section 1877(c) of the Act. Although we are aware of no public comment regarding publicly traded securities which are traded under an automated interdealer quotation system operated by the NASD, it has come to our attention that the NASD no longer exists and that it is no longer possible to purchase a publicly traded security traded under the automated interdealer quotation system it formerly operated. In response, we investigated whether we could modernize the exception for ownership of publicly traded securities by including currently existing systems that are equivalent to the NASD's now-obsolete automated interdealer quotation system.

In 1972, NASD launched a computerized stock trading system called the National Association of Securities Dealers Automated Quotation Systems (NASDAQ) stock market. In 2000, NASDAQ became an independent entity. In 2007, the United States Securities and Exchange Commission approved the formation of a new self-regulatory organization, the Financial Industry Regulatory Authority (FINRA), to be a successor to the NASD. The NASD and the member regulation, enforcement, and arbitration functions of the NYSE consolidated to form FINRA. Until November 2014, FINRA operated a quotation medium for over-the-counter (OTC) securities, including those not listed on NASDAQ or a national stock exchange. We are unable to locate a definition of ''automated interdealer quotation system'' and believe this is an antiquated term for which there is no modern day equivalent. However, we believe that electronic stock markets such as NASDAQ and FINRA's OTC market are outgrowths and modern day equivalents to an automated interdealer quotation system.

We propose to use our authority in section 1877(b)(4) of the Act to revise the regulations at § 411.356(a)(1) to include securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent. Trades made through a physical exchange (such as the NYSE or the American Stock Exchange) are standardized and publicly transparent. To protect against risk of program or patient abuse, we believe that trades on the electronic stock markets and OTC quotation systems that are eligible for this exception must also be standardized and publicly transparent. Accordingly, we are not proposing to include any electronic stock markets or OTC quotation systems that trade unlisted stocks or that involve decentralized dealer networks. We also believe it is appropriate to limit the proposed exception to those electronic stock markets or OTC quotation systems that publish quotations on a daily basis, as physical exchanges must publish on that basis. We seek comment regarding whether fewer, different, or additional restrictions on electronic stock markets or OTC quotation systems are necessary to effectuate the Congress' intent and to protect against patient or program abuse.

6. New Exception for Timeshare Arrangements

a. Statutory and Regulatory Background

Section 1877(e)(1)(A) of the Act sets forth an exception for the rental of office space. Under this exception, lease arrangements must satisfy six specific criteria, one of which is that the office space rented or leased is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any other person or entity related to the lessor). The exception also permits payments by the lessee for the use of space consisting of common areas (which do not afford exclusive use to the lessee) if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. The 1995 final rule (60 FR 41959) incorporated the provisions of section 1877(e)(1)(A) of the Act into our regulations at § 411.357(a).

Section 1877(e)(8) of the Act sets forth an exception for: (1) Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services; and (2) payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value (the ''payments by a physician exception''). The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at § 411.357(i). In the 1998 proposed rule (63 FR 1703), we proposed to interpret ''other items or services'' to mean any kind of items or services that a physician might purchase, but not including clinical laboratory services or those specifically excepted under another provision in §§ 411.355 through 411.357. In that proposal, we stated that we did not believe that the Congress meant for the payments by a physician exception to cover a rental arrangement as a service that a physician might purchase, because it had already included in the statute specific exceptions, with specific standards for such arrangements, in section 1877(e)(1) of the Act. In Phase II (69 FR 16099), we responded to commenters that disagreed with our position that the exception for payments by a physician is not available for

arrangements involving items and services addressed by another exception, stating that our position is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception from negating the statute (69 FR 16099). We made no changes to the exception in Phase II to accommodate the commenters' concerns.

In the 1998 proposed rule (63 FR 1699), we proposed an exception for compensation arrangements that are based upon fair market value and meet certain other criteria. We finalized the exception at § 411.357(l) in Phase I, noting that, although it only covered services provided by a physician (or an immediate family member of a physician) to an entity furnishing DHS, it was available for some arrangements that are covered by other exceptions (66 FR 917 through 919). Although commenters requested that we expand the exception to cover the transfer, lease or license of real property, intangible property, property rights, or a covenant not to compete (69 FR 16111), we made no substantive changes to the exception for fair market value compensation in Phase II. In Phase III, we expanded the exception at § 411.357(l) for fair market value compensation to include arrangements involving compensation from a physician to an entity furnishing DHS. We reiterated that the exception for fair market value compensation does not protect office space lease arrangements; rather, arrangements for the rental of office space must satisfy the requirements of the exception at § 411.357(a) (72 FR 51059 through 51060).

In Phase III, a commenter suggested that ''timeshare'' leasing arrangements would be addressed more appropriately in the exception for fair market value compensation at § 411.357(l) or the exception for payments by a physician at § 411.357(i), instead of the exception for the rental of office space at § 411.357(a) (72 FR 51044). The commenter described a timeshare lease arrangement under which a physician or group practice pays the lessor for the right to use office space exclusively on a turnkey basis, including support personnel, waiting area, furnishings, and equipment, during a schedule of time intervals for a fair market value rate per interval of time or in the aggregate, and urged us to clarify that such timeshare arrangements may qualify under § 411.357(i) or § 411.357 (l), the exceptions for payments by a physician and fair market value compensation, respectively. We note that the commenter specifically described arrangements where the lessee had exclusive, but only periodic, use of the premises, equipment, and personnel. In response, we declined to permit space leases to be eligible for the fair market value exception at § 411.357(l), and stated that we were not persuaded that § 411.357(i) should protect space leases (72 FR 51044 through 51045).

b. Timeshare Arrangements

Through our administration of the SRDP, as well as stakeholder inquiries, we have been made aware of arrangements for the use of a licensor's premises, equipment, personnel, items, supplies or services by physicians who, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement. For example, in a rural or underserved area, there may be a need in the community for certain specialty services but that need is not great enough to support the full-time services of a physician specialist. Under timeshare arrangements, a hospital or local physician practice may ask a specialist from a neighboring community to provide the services in space owned by the hospital or practice on a limited or as-needed basis. Most often, under such an arrangement, the specialist does not establish an additional medical practice office by renting office space and equipment, hiring personnel, and purchasing services and supplies necessary for the operation of a medical practice. Rather, it is common for a hospital or local physician practice to make available to the visiting independent physician on a ''timeshare'' basis the space, equipment and services necessary to treat patients. Under the timeshare arrangement, the hospital or physician practice may provide the physician with a medical office suite that is fully furnished and operational. The physician does not need to make any improvements to the space or to bring any medical or office supplies in order to begin seeing patients. Timeshare arrangements also may be attractive to a relocating physician whose prior medical practice office lease has not expired or to a new physician establishing his or her medical practice.

It is our understanding that a license to use the property of another person differs from a lease in that ownership and control of the property remains with the licensor. That is, a lease transfers dominion and control of the property from the lessor to the lessee, but a license is a mere privilege to act on another's property and does not confer a possessory interest in the property. We recognize that timeshare arrangements may differ from traditional lease and service arrangements. Often, a timeshare arrangement does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of the licensor to the licensee, but rather confers a privilege (or license) to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the license.

c. New Exception

Because timeshare arrangements generally include the use of office space, under our current regulations, an arrangement as it relates to office space must be analyzed under the exception for the rental of office space. However, where a timeshare arrangement is structured as a license to use the office space (and other property and personnel) of the licensor, it cannot satisfy the requirements of that exception because a license generally does not provide for exclusive use of the premises. Moreover, the arrangement may have a term of less than 1 year, which would not satisfy the term requirement at § 411.357(a)(2). The exceptions for payments by a physician and fair market value compensation arrangements, which do not have exclusive use or 1-year term requirements, are unavailable under our current regulations because of the inclusion of office space in the bundle of items and services in a typical timeshare arrangement.

We believe that timeshare arrangements that include the use of office space can be structured in a way that does not pose a risk of program or patient abuse. To address such arrangements, which we believe are often necessary to ensure adequate access to needed specialty care (especially in rural and underserved areas), we are using our authority at section 1877(b)(4) of the Act to propose a new exception at § 411.357(y) that would protect timeshare arrangements that meet certain criteria, including that: (1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement; (2) the arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor's premises, equipment, personnel, items, supplies, or services; (3) the licensed premises, equipment, personnel, items, supplies, and services are used predominantly to furnish evaluation and management services to

patients of the licensee; (4) the equipment covered by the arrangement, if any: (i) Is located in the office suite where the physician performs evaluation and management services, (ii) is used only to furnish DHS that is incidental to the physician's evaluation and management services and furnished at the time of such evaluation and management services, and (iii) is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests); (5) the arrangement is not conditioned on the licensee's referral of patients to the licensor; (6) the compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; (7) the arrangement would be commercially reasonable even if no referrals were made between the parties; and (8) the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any federal or state law or regulation governing billing or claims submission.

The proposed exception at § 411.357(y) would apply only to timeshare arrangements where the licensor is a hospital or physician organization; it would not protect arrangements where the licensor is another type of DHS entity. We believe that timeshare arrangements offered by independent diagnostic testing facilities and clinical laboratories, in particular, pose a heightened risk of program or patient abuse as they may serve to lock in referral streams from the physician licensee as a result of the physician's proximity to the DHS furnished by such entities. We do not believe that it is necessary to protect arrangements with these types of entities in order to achieve the goals of beneficiary access to care and improved outcomes. Similarly, we see no reason to protect timeshare arrangements in which the hospital or other entity furnishing DHS is the licensee and the referring physician is the licensor. We seek comment regarding whether the scope of the exception is sufficiently broad to improve beneficiary access to care (especially in rural or underserved areas), whether there is a compelling need to allow DHS entities other than hospitals and physician organizations to enter into timeshare arrangements with referring physicians, and whether the exception should apply if the licensor is a physician who is a source of DHS referrals to the licensee. We solicit comment on whether the exception should be limited to arrangements in rural and underserved areas.

We propose to protect only those timeshare arrangements under which the physician uses the licensed premises, equipment, personnel, items, supplies, and services predominantly for the evaluation and management of patients. The proposed exception at § 411.357(y) would not protect the license of office space used by the physician solely or primarily to furnish DHS to patients. We seek comment regarding whether ''predominant use'' is an appropriate measure of the use of the licensed premises and, if so, how we might define this standard, or whether we should include a different measure, such as one that would require that ''substantially all of the services furnished to patients on the licensed premises are not DHS.'' We also propose to limit the type and location of the equipment that may be licensed to only that which is used to furnish DHS that is incidental to the patient's evaluation and management visit and furnished contemporaneously with that visit. We note that this requirement does not affect the manner in which the DHS is billed (for example, ''incident to'' a physician's service or directly by a nonphysician practitioner). We believe that DHS that is ''incidental to'' the patient's evaluation and management includes a limited universe of diagnostic tests and other procedures, such as x-rays, rapid strep tests, and urine dipstick tests to diagnose pregnancy, that assist the physician in his or her diagnosis and treatment of the patient. For this reason, we propose to exclude from the protection of the exception the license of advanced imaging equipment, radiation therapy equipment, and clinical and pathology laboratory equipment (other than that which is used to furnish CLIA-waived laboratory tests). Finally, we propose to require that the equipment be located on the licensed premises; that is, in the office suite. For example, it is reasonable for an orthopedic surgeon to x-ray a patient to assist in the diagnosis and treatment of the patient's potential orthopedic injury or condition. Under the proposed exception, a hospital may license to the orthopedic surgeon the use of medical office space, an in-suite x-ray machine, an x-ray technician, and office and medical supplies, provided that all of the other requirements of the exception are satisfied. We seek comment on these requirements and limitations. Specifically we are interested in comments regarding whether the equipment location requirement should be expanded to include equipment located in the same building (as defined at § 411.351) as the licensed office suite or an off-site location, and whether we should prohibit the license of equipment in the absence of a corresponding license of office space.

We also propose to prohibit certain per unit-of-service and percentage compensation methodologies for determining the license fees under timeshare arrangements. Under the new exception, parties would be able to determine license fees on an hourly, daily, or other time-based basis, but would not be permitted to use a compensation methodology based on, for example, the number of patients seen. Parties also would not be permitted to use a compensation methodology based on the amount of revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the licensee while using the licensor's premises, equipment, personnel, items, supplies or services. We are soliciting comments on whether these limitations on compensation methodologies for license fees are necessary and whether a timeshare arrangement for the use of a licensor's premises, equipment, personnel, items, supplies or services would pose a risk of program or patient abuse in the absence of this prohibition on per-click and percentage compensation methodologies for the license fees paid by the licensee to the licensor.

We note that the exception for the rental of office space would continue to be the only exception that would apply to traditional office space lease arrangements where dominion and control of the premises is transferred to the lessee for a specified period of time for the lessee's exclusive use of the leased premises. The proposed new exception would also not be available to protect part-time exclusive use office space *lease* arrangements. We solicit comments on the proposed new exception for timeshare arrangements and any additional criteria that may be necessary to safeguard against program or patient abuse.

7. Temporary Noncompliance With Signature Requirements (§ 411.353(g))

Several compensation arrangement exceptions to the physician self-referral law require that an arrangement be signed by the parties. Our current regulations at § 411.353(g) include a special rule for arrangements involving temporary noncompliance with signature requirements. The regulation permits an entity to submit a claim or

bill and receive payment for DHS if an arrangement temporarily does not satisfy the applicable exception's signature requirement but otherwise fully complies with the exception. Under the current rule, if the failure to comply with the signature requirement is inadvertent, the parties must obtain the required signature(s) within 90 days. If the failure to comply is not inadvertent, the parties must obtain the required signature(s) within 30 days.

In the FY 2009 IPPS final rule, we stated that we would evaluate our experience with the regulation at § 411.353(g) and propose more or less restrictive modifications at a later date (73 FR 48707). We are now proposing to modify the current regulation to allow parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent. We recognize that it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures. We are also proposing to revise § 411.353(g) to include reference to the new regulatory exceptions for payments to a physician to employ a nonphysician practitioner and timeshare arrangements that we are proposing at new § 411.357(x) and § 411.357(y), respectively, to ensure that all compensation exceptions with signature requirements are treated uniformly. We do not believe that allowing parties 90 days to obtain signatures while the arrangement otherwise complies with the physician self-referral law poses a risk of program or patient abuse.

The proposed regulation maintains the safeguards of the current rule. Specifically, the proposed regulation applies narrowly to the signature requirement only. To make use of the proposed revised provisions at § 411.353(g), an arrangement would have to satisfy all other requirements of an applicable exception, including the requirement that the arrangement be set out in writing. In addition, an entity may make use of the proposed regulation only once every 3 years with respect to the same referring physician. Given these safeguards, we believe that the proposed revision poses no risk of program or patient abuse.

8. Physician-Owned Hospitals

Section 6001(a) of the Affordable Care Act amended the rural provider and hospital ownership or investment interest exceptions to the physician self-referral law to impose additional restrictions on physician ownership and investment in hospitals. For purposes of these exceptions, the new legislation defined a ''physician owner or investor'' as a physician, or immediate family member of a physician, who has a direct or indirect ownership or investment interest in a hospital. We refer to hospitals with direct or indirect physician owners or investors as ''physician-owned hospitals.''

Section 6001(a)(3) of the Affordable Care Act established new section 1877(i) of the Act, which imposes additional requirements for physician-owned hospitals to qualify for the rural provider or hospital ownership exceptions. In part, section 1877(i) of the Act requires a physician-owned hospital to disclose the fact that the hospital is partially owned or invested in by physicians on any public Web site for the hospital and in any public advertising for the hospital; provides that a physician-owned hospital must have had a provider agreement in effect as of December 31, 2010; and provides that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we addressed many of the additional requirements that were established by the Affordable Care Act for a physician-owned hospital to avail itself of the rural provider or hospital ownership exceptions. In that final rule with comment period, among other things, we finalized regulations at § 411.362(b)(3)(ii)(C) that required a physician-owned hospital to disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. We also finalized regulations at § 411.362(b)(1) that required a physician-owned hospital to have had a provider agreement in effect on December 31, 2010, and at § 411.362(b)(4)(i) to provide that the percentage of the total value of the ownership or investment interests held in a hospital (or in an entity whose assets include the hospital) by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010. We also revised the rural provider and hospital ownership exceptions at § 411.356(c)(1) and § 411.356(c)(3), respectively, to provide that a physician-owned hospital must meet the requirements in new § 411.362 not later than September 23, 2011, in order to avail itself of the applicable exception.

a. Preventing Conflicts of Interest: Public Web Site and Public Advertising Disclosure Requirement (§ 411.362(b)(3)(ii)(C))

Following publication of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we received numerous inquiries about many of the additional requirements that were established by the Affordable Care Act for the rural provider and hospital ownership exceptions, including the requirement that a physician-owned hospital must disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. Specifically, industry stakeholders requested additional guidance to clarify the terms ''public Web site for the hospital'' and ''public advertising for the hospital,'' the range of statements that constitute a sufficient disclosure, and the period of noncompliance for a failure to disclose. We also received disclosures through the SRDP where the disclosing parties reasonably assessed that, based on existing CMS guidance, they could not certify compliance with this disclosure requirement and, therefore, the conduct constituted a violation of the law.

Given the inquiries and disclosures that we received, we have carefully considered both the disclosure requirement's purpose and our existing regulations addressing the requirement. We believe that, in establishing this requirement, the Congress decided that the public should be on notice if a hospital is physician-owned because that fact may inform an individual's medical decision-making. We do not interpret the public Web site and advertising disclosure requirements to be prescriptive requirements for the inclusion of specific wording in an undefined range of communication. Accordingly, we are proposing to provide physician-owned hospitals more certainty regarding the forms of communication that require a disclosure statement and the types of language that would constitute a sufficient statement of physician ownership or investment. We believe that our proposals would appropriately balance the industry's need for greater clarity with the public's need to be apprised of such information. Finally, we note that, in the event that a physician-owned hospital discovers that it failed to satisfy the public Web site or public advertising disclosure requirements, the SRDP is the appropriate means for reporting such overpayments. For more information, see the *Special Instructions for Submissions to the CMS Voluntary Self-*

Referral Disclosure Protocol for Physician-Owned Hospitals and Rural Providers that Failed to Disclose Physician Ownership on any Public Web site and in any Public Advertisement, available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html*.

For the public Web site disclosure requirement, we are proposing to amend existing § 411.362(b)(3)(ii)(C) to list examples of the types of Web sites that do not constitute a ''public Web site for the hospital.'' We are proposing to revise § 411.362(b)(3)(ii)(C) to specify that a ''public Web site for the hospital'' does not include certain types of Web sites, even though limited information about the hospital may be found on such Web sites. For example, we do not consider social media Web sites to be ''public Web sites for the hospital,'' and the proposed regulation would clarify this. We do not believe that a hospital's communications (such as maintaining an individual page on a Web site, posting a video, or posting messages) via a social media Web site should be construed as a Web site that is ''for the hospital,'' given that the Web site is operated and maintained by a social networking service and that a multitude of users typically can become members of such a service. Further, we note that social media communications, which are used primarily for the development of social and professional contacts and for sharing information between interested parties, differ in scope from the provision of information typically found on a hospital's main Web site, such as the hospital's history, leadership and governance structure, mission, and a list of staff physicians. We also propose to specify at § 411.362(b)(3)(ii)(C) that a ''public Web site for the hospital'' does not include electronic patient payment portals, electronic patient care portals, or electronic health information exchanges, as these are not available to the general public. These portals are for the convenience of only those patients who have already been treated at the hospital and to whom the hospital's physician ownership likely would have already been disclosed. Our proposed examples of Web sites that do not constitute a ''public Web site for the hospital'' is not exhaustive. We recognize the difficulty in identifying every type of Web site that either currently exists or may emerge as technology develops that would not require a disclosure statement. We seek public comment on whether our proposed examples are appropriate given the statutory language and whether we should include different or additional examples of Web sites in the list. We also seek public comment on whether, in the alternative, we should provide an inclusive definition of what would be considered a ''public Web site for the hospital'' and, if so, we solicit recommendations for such a definition. Finally, we note that, even if a Web site does not constitute a public Web site for the hospital under our proposal, the online content may, depending on the facts and circumstances, constitute public advertising for the hospital that would require a disclosure statement.

For the public advertising disclosure requirement, we are proposing to define ''public advertising for the hospital'' at § 411.362(a). We note that our existing regulations at § 411.362(b)(3)(ii)(C) reference ''public advertising'' without explicitly specifying ''for the hospital,'' which is different from the statutory language of section 1877(i)(1)(C)(iv) of the Act. We are proposing to include that phrase in the definition and in the disclosure requirement to conform our regulations to the statutory language. To determine how best to clarify what we consider to be ''public advertising for the hospital,'' we consulted numerous sources for definitions of ''advertise'' and ''advertising.'' After considering the results of our research, we are proposing to define ''public advertising for the hospital,'' for purposes of the physician self-referral law, as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital. We are proposing that the definition of ''public advertising for the hospital'' does not include, by way of example, communication made for the primary purpose of recruiting hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital. We believe that, as a general matter, communications related to recruitment are for the primary purpose of fulfilling a hospital's basic need for staff and that communications issued via public service announcements and community outreach are for the primary purpose of providing the general public healthcare-related information. Therefore, we are proposing to specify in our regulations that these types of communications would be excluded from our proposed definition of ''public advertising for the hospital.'' We note that these types of communications do not represent an exhaustive list of what we do not consider ''public advertising for the hospital.'' We seek public comment on our proposed definition of ''public advertising for the hospital'' as well as our proposed list of examples that do not constitute ''public advertising for the hospital.''

We note that a determination as to whether a certain communication constitutes public advertising for the hospital depends on the specific facts and circumstances of the communication. In the CY 2011 OPPS/ASC final rule with comment period, commenters asserted that a hospital should not be required to include disclosures in certain advertising, such as the kind found on billboards, or the kind aired via radio and television and that the requirement should be confined to print media such as newspapers, magazines, and other internally produced print material for public use (75 FR 72248). In response to the commenters, we stated that we have no flexibility to exclude certain types of advertising media, as the statute was very straightforward in its statement that the disclosure appear in ''any public advertising'' for the hospital. In this proposed rule, we are clarifying that the facts and circumstances of the communication, rather than the medium by which the message is communicated, determine whether a communication constitutes ''public advertising for the hospital.''

We also are proposing to clarify the types of statements that constitute a sufficient statement of physician ownership or investment. Specifically, we propose to amend § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment. A statement such as ''this hospital is owned or invested in by physicians'' or ''this hospital is partially owned or invested in by physicians'' would certainly meet this standard. However, statements that the hospital is ''founded by physicians,'' ''managed by physicians,'' ''operated by physicians,'' or ''part of a health network that includes physician-owned hospitals'' would also meet this standard. We also believe that a hospital's name, by itself, could constitute language that meets this standard. For example, we believe that ''Doctors Hospital at Main Street, USA'' would put a reasonable person on notice that the hospital may be physician-owned. We seek public comment on our proposed revision to the public Web site and advertising disclosure requirements and on our proposed examples of language that would satisfy that standard. We also invite suggestions

regarding alternative standards for deeming language sufficient for these requirements.

For the location and legibility of disclosure statements, we continue to believe, as stated in the CY 2011 OPPS/ASC final rule with comment period, that the disclosure should be located in a conspicuous place on the Web site and on a page that is commonly visited by current or potential patients, such as the home page or ''about us'' section (75 FR 72248). Further, we believe that the disclosure should be displayed in a clear and readable manner and in a size that is generally consistent with other text on the Web site. We do not propose here to prescribe a specific location or font size for disclosure statements on either a public Web site or public advertising; rather, physician-owned hospitals have flexibility in determining exactly where and how to include the disclosure statements, provided that the disclosure would put a reasonable person on notice that the hospital may be physician-owned.

For those physician-owned hospitals that have identified non-compliance with the public Web site disclosure requirement, we are taking this opportunity to clarify that the period of noncompliance is the period during which the physician-owned hospital failed to satisfy the requirement. We note that September 23, 2011 is the date by which a physician-owned hospital had to be in compliance with the public Web site and advertising disclosure requirements (75 FR 72241), and, therefore, would be the earliest possible beginning date for noncompliance. For those physician-owned hospitals that have identified noncompliance with the public advertising disclosure requirement, we are clarifying that the period of noncompliance is the duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date. For example, if a hospital pays for an advertisement to be included in one issue of a monthly magazine and the hospital fails to include the disclosure in the advertisement, the period of noncompliance likely would be the applicable month of circulation, even if the magazine continued to be available in the archives of the publisher, in waiting rooms of physician offices, or other public places. We seek public comment on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

b. Determining the *Bona Fide* Investment Level (§ 411.362(b)(4)(i))

As stated above, section 6001(a)(3) of the Affordable Care Act established new requirements for physician-owned hospitals to avail themselves of either the rural provider or hospital ownership exceptions to the physician self-referral law, including the requirement that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010. In this proposed rule, we refer to the percentage of ownership or investment interests held by physicians in a hospital as the ''*bona fide* investment level'' and such percentage that was set as of March 23, 2010, as the ''baseline *bona fide* investment level.''

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we codified the *bona fide* investment requirement at § 411.362(b)(4)(i). In that final rule we responded to commenters that asserted that the *bona fide* investment level should be calculated without regard to any ownership or investment interests held by physicians who do not make any referrals to the hospital, including physicians who are no longer practicing medicine (75 FR 72250). We stated that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline physician ownership level. In our response, we noted that section 1877(i)(5) of the Act defines ''physician owner or investor'' for purposes of that subsection to include any physician with a direct or indirect ownership or investment interest in the hospital and that, under our definition of ''indirect ownership or investment interest'' at § 411.354(b)(5), only ''referring physicians'' can have an indirect ownership or investment interest in a DHS entity. Although we did not explicitly address direct ownership or investment interests in our response, we note that only referring physicians can have a direct financial relationship under our existing regulations at § 411.354(a)(2)(i).

Following publication of the CY 2011 OPPS/ASC final rule with comment period, we received inquiries from industry stakeholders regarding our statement that the baseline *bona fide* investment level need not be calculated as including the ownership or investment interests of non-referring physicians. First, the stakeholders asserted that the statutory definition of physician owner or investor is broad and that if the Congress had intended to limit the definition to only referring physicians, the Congress would have included such qualifying language, as it did in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Second, the stakeholders asserted that including only referring physicians in the definition of physician owner or investor for purposes of establishing the baseline *bona fide* investment level frustrates the purpose of an explicit deadline set forth in the statute. The stakeholders noted that in the Affordable Care Act, the Congress required physician-owned hospitals that seek to avail themselves of the rural provider or hospital ownership exceptions to have had physician ownership or investment as of March 23, 2010, but allowed them until December 31, 2010 to obtain a provider agreement. The stakeholders asserted that our position makes the March 23, 2010 deadline meaningless because a pre-operational physician-owned hospital that did not have a provider agreement until December 31, 2010 likely would not have had physician owners or investors referring to the hospital as of the March 23 date. The stakeholders stated that our position regarding non-referring physicians in the CY 2011 OPPS/ASC final rule with comment period, in effect, precluded pre-operational hospitals from satisfying the requirement for physician ownership as of March 23, 2010, thus preventing the hospitals from availing themselves of the hospital ownership or rural provider exceptions.

Given the inquiries that we received after publication of the CY 2011 OPPS/ASC final rule with comment period, we have reconsidered our position that our regulations at § 411.354 necessarily limit the definition of physician owner or investor for purposes of establishing the baseline *bona fide* investment level (and any *bona fide* investment level thereafter). As we stated in the CY 2011 OPPS/ASC final rule with comment period, we recognize that the statutory definition of physician owner or investor is broad (75 FR 72250). Further, we understand the concern expressed by the stakeholders that our position may frustrate an explicit statutory deadline for certain physician-owned hospitals. We believe that the statutory revisions to the rural provider and hospital ownership exceptions must be read harmoniously and not in a way that makes any provision meaningless. Accordingly, we are proposing to revise our policy articulated in the CY 2011

OPPS/ASC final rule with comment period to require that the baseline *bona fide* investment level and the *bona fide* investment level include direct and indirect ownership and investment interests held by a physician if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351, regardless of whether the physician refers patients to the hospital (and therefore, irrespective of whether he or she is a ''referring physician'' for purposes of our regulatory definition of ownership or investment interest at § 411.354). Further, under our proposal, the direct or indirect ownership interests held by an individual who no longer practices medicine, as described in the comment summary above, would be counted if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351. We seek public comment regarding non-referring physicians and the *bona fide* investment level, including whether our proposal might alleviate the burden that some physician-owned hospitals reported when trying to determine whether a particular physician was a referring or non-referring physician for purposes of establishing their baseline *bona fide* investment levels and the *bona fide* investment levels generally.

In order to support our proposal and implement the requirements of the statute, we are proposing to amend our existing regulations to specify that, for purposes of § 411.362 (including for purposes of determining the baseline *bona fide* investment level and the *bona fide* investment level thereafter), the ownership or investment interests held by both referring and non-referring physicians are included. We propose to effectuate this change by establishing a definition of ownership or investment interest solely for purposes of § 411.362 that would apply to all types of owners or investors, regardless of their status as referring or non-referring physicians. Specifically, we propose to define ''ownership or investment interest'' at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the proposed revision, a direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an indirect ownership or investment interest in a hospital exists if: (1) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital. We are also proposing that an indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain. As used in § 411.362, the term ''physician'' would continue to have the meaning set forth in § 411.351; that is, an individual who meets the definition of ''physician'' set forth in section 1861(r) of the Act.

We believe that our proposed revision would make the prohibition set forth at § 411.362(b)(4)(i) consistent with the statutory definition of ''physician owner or investor'' in a hospital without unsettling long-standing definitions in our regulations. We seek public comment on our proposed revision to § 411.362, including whether such revision would adequately address the concerns expressed by the stakeholders after publication of the CY 2011 OPPS/ASC final rule with comment period.

We seek public comment on an alternate proposal that we believe also supports our policy and, thereby, effectuates the statute's purpose. Specifically, we seek public comment on whether, in the alternative, we should revise our regulations in an even more comprehensive manner and remove the references to a ''referring physician'' throughout existing § 411.354. We invite public comment on whether it would be helpful to retain the references to a ''referring physician'' for those specific provisions where the concept of a physician's referrals to a DHS entity is essential to the provision, such as our definition of an indirect compensation arrangement at § 411.354(c)(2)(ii).

Finally, we recognize that some physician-owned hospitals may have relied on the position that was articulated in the CY 2011 OPPS/ASC final rule with comment period concerning non-referring physicians and the baseline *bona fide* investment level. If we finalize one or more of the proposals described in this section of the proposed rule, these hospitals may have revised *bona fide* investment levels that exceed the baseline *bona fide* investment levels calculated under our current guidance. Therefore, we propose to delay the effective date of the new regulation until such time as physician-owned hospitals would have sufficient time to come into compliance with the new policy. For example, we could delay the effective date for 1 year from the date of publication in the **Federal Register** of the rulemaking in which we finalize the new regulation or on a specific date, such as January 1, 2017. We solicit comment on how long we should delay the effective date. We also seek comment on the impact of our proposed regulatory revisions on physician-owned hospitals and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with our proposed revisions.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

a. Background

In the 1998 proposed rule, we discussed the impetus for the physician self-referral law (63 FR 1662), noting that both the anti-kickback statute and section 1877 address Congress' concern that health care decision making can be unduly influenced by a profit motive. When physicians have a financial incentive to refer, 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 can be affected 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 since new competitors can no longer win business with superior quality, service, or price.

The referral and billing prohibitions of the statute (and the corresponding prohibitions in § 411.353) are intended to address these concerns, which remain valid today. (See section P.1. of this proposed rule for a detailed description of the prohibitions.) As explained elsewhere in this proposed rule, the prohibitions are absolute unless the financial relationship between the physician and entity to which he or she refers DHS satisfies the requirements of an applicable exception. The Congress provided for certain exceptions in sections 1877(b), (c), (d) and (e) of the Act, and granted the Secretary authority to establish additional exceptions for financial relationships that do not pose a risk of program or patient abuse. The Secretary has used the authority in

section 1877(b)(4) of the Act to establish numerous exceptions and has interpreted statutory and regulatory provisions in numerous rulemakings.

Many of the exceptions in section 1877(e) of the Act (''Exceptions Relating to Other Compensation Arrangements'') include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the ''volume or value'' and ''other business generated'' standards.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a group of physicians must meet to qualify as a ''group practice'' (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699). In the discussion of group practices, we stated that ''[w]e believe that the 'volume or value' standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services'' (63 FR 1690). We went on to state that ''[t]he most straightforward way for a group to demonstrate that it is meeting the requirements [for group practices] would be for the group to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients'' (63 FR 1690). However, because our definition of ''referral'' at § 411.351 includes only referrals for DHS, ''a group that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions related to referrals for [DHS] for Medicare and Medicaid patients'' (63 FR 1690). As noted in this section of the proposed rule, outside the group practice context, these principles apply generally to compensation from a DHS entity to a physician.

We also addressed the ''other business generated'' standard in the 1998 proposed rule, stating that we believe that the ''Congress may not have wished to except arrangements that include additional compensation for other business dealings'' and that ''[i]f a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions'' (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value and other business generated standards, responding to comments on our proposals in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulae (66 FR 876). We also stated that the phrase ''does not take into account other business generated between the parties'' means that ''the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid DHS or any other business generated by the referring physician, including other Federal and private pay business'' (66 FR 877), noting that the phrase ''generated between the parties'' means ''business generated by the referring physician'' for purposes of the physician self-referral law (66 FR 876). In Phase II, we clarified that personally performed services are not considered ''other business generated'' by the referring physician (69 FR 16068). ''Simply stated, section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician's ability to generate other revenue'' (66 FR 877). This remains our position, and we continue to apply this interpretation of the volume or value and other business generated standards uniformly to all provisions under section 1877 of the Act and part 411, subpart J, where the language appears. (See 66 FR 877.)

Also in Phase I, we established special rules on compensation at § 411.354(d) that deem compensation not to take into account the volume or value of referrals or other business generated between the parties if certain conditions are met (66 FR 876–77). These rules state that compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS. Compensation will be deemed not to take into account other business generated between the parties to a compensation arrangement if the compensation is fair market value and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. Both special rules apply to time-based or per-unit of service-based (per-click) compensation formulae. However, as we noted in Phase II, the special rules on compensation are intended to be safe harbors and there may be some situations not described in § 411.354(d) where an arrangement does not take into account the volume or value of referrals (69 FR 16070).

b. Changes in Health Care Delivery and Payment Systems Since the Enactment of the Physician Self-Referral Law

Since the enactment of section 1877 of the Act in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-federal payors and patients. For over a decade, we have engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Deficit Reduction Act of 2005 (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) have guided our efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test models to implement these reforms. We highlight a few of the Affordable Care Act's notable provisions in this section of this proposed rule.

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing (VBP) program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we base each hospital's value-based payment percentage on the hospital's Total

Performance Score (TPS) for a specified performance period. (See 79 FR 49853, 50048.) A TPS score is awarded to hospitals during a VBP period (established as a fiscal year) and is derived from four domains: Clinical Process of Care, Patient Experience of Care, Outcome, and Efficiency. For more detailed information about each TPS domain, see our regulations at § 412.165(b); for more information regarding how TPS scores are calculated, see *http://www.medicare.gov/hospitalcompare/data/total-performance-scores.html*. As noted, participation in the Hospital VBP is mandatory.

Section 3021 of the Affordable Care Act, codified at section 1115A of the Act, established the Center for Medicare and Medicaid Innovation (CMMI) within CMS. The purpose of CMMI is to test innovative payment and service delivery models to reduce the cost of care provided to patients in the Medicare and Medicaid programs while preserving or enhancing the quality of care furnished to Medicare and Medicaid patients. Using its authority in section 1115A of the Act, CMMI has begun testing numerous health care delivery and payment models, including the Pioneer Accountable Care Organization (ACO) model, four models of the Bundled Payment for Care Improvements Initiative (BPCI), the Nursing Home Value-based Purchasing Demonstration, and the Community-based Care Transitions Program. Participation in these models is voluntary. For more information about CMMI's innovation models, see *http://innovation.cms.gov/initiatives/index.html#views=models*.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (MSSP). The Congress created the MSSP to facilitate coordination and cooperation among providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the MSSP by creating or participating in an ACO. The MSSP will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care. Participation in the MSSP is voluntary. For more information about the MSSP, see *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html*.

Outside of the programs established or authorized under the laws noted above, we are moving away from Medicare payments to providers and suppliers that do not incorporate the value of the care provided. The Secretary recently set a goal of tying 30 percent of traditional, fee-for-service Medicare payments to quality or value through alternative payment models, such as ACOs or bundled payment arrangements, by the end of 2016, and 50 percent of payments to these models by the end of 2018. The Secretary also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016, and 90 percent of payments to quality or value by 2018, through programs such as the Hospital VBP Program and the Hospital Readmissions Reduction Program. (See press release titled ''Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value,'' U.S. Department of Health & Human Services (Jan. 26, 2015), *http://www.hhs.gov/news/press/2015pres/01/20150126a.html*.)

Value-based payment models and similar programs are receiving attention in the commercial payor sector as well. Some of the largest private carriers have made significant efforts to transition from fee-for-service models to global payment systems. For example, in 2009, Blue Cross and Blue Shield of Massachusetts (BC/BS Massachusetts) launched the Alternative Quality Contract (AQC), replacing a fee-for-service model with a modified global payment model for payments to hospitals and physicians. The AQC model merges a per-patient global budget with performance incentives based on national measures linked to health outcomes, quality, and patient satisfaction. The AQC model now includes approximately 85 percent of the hospitals and physicians in the BC/BS Massachusetts HMO network. (See Alternative Quality Contract, Blue Cross Blue Shield of Massachusetts *https://www.bluecrossma.com/visitor/about-us/affordability-quality/aqc.html*.) The AQC program initiated by BC/BS Massachusetts has met with initial success as shown in a 4-year study published in the New England Journal of Medicine in 2014. (See Song, Zuri, et al., Changes in Health Care Spending and Quality 4 Years into Global Payment, N. Engl. J. Med 371; 18, Oct. 30, 2014, *http://www.nejm.org/doi/full/10.1056/NEJMsa1404026#t=article*.) Specifically, the study found that spending grew an average of $62.21 per enrollee per quarter less in the AQC model contingent than in a control group. Similarly, in 2011, Blue Cross Blue Shield of Minnesota began a 3-year partnership with large health care providers within Minnesota to improve quality and lower costs through an Aligned Incentive Contracting Model. Under that model, increases to the fee-for-service components of payments decrease over time and are replaced by growing performance incentives tied to measurable improvements in quality outcomes and to managing total cost of care. (See Blue Plans Improving Healthcare Quality and Affordability through Innovative Partnerships with Clinicians, BlueCross BlueShield Association, Feb. 13, 2014, *http://www.bcbs.com/healthcare-news/press-center/BP-and-Quality-and-Plan-Innovations.pdf*.)

c. Financial Relationships in Alternative Delivery and Payment Systems

The physician self-referral law, by design, separates entities furnishing DHS from the physicians who refer Medicare patients to them. Evolving health care delivery and payment models, within both the Medicare and Medicaid programs and programs sponsored by non-federal payors, are premised on the close integration of a variety of different health care providers in order to achieve the goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care, often referred to as the ''three-part aim.'' Entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law's prohibitions if they wish to compensate physicians to help them meet the triple aim and avoid financial penalties that may be imposed on low-value health care providers. Because all inpatient and outpatient services are considered DHS, hospitals must consider each and every service referred by a physician in their attempts to ensure that compensation paid to a physician does not take into account the volume or value of his or her referrals to the hospital. According to stakeholders, structuring incentive compensation and other payments can be particularly challenging for hospitals, even where the payments are to hospital-employed physicians.

Stakeholders have expressed concern that, outside of the MSSP or certain CMMI-sponsored care delivery and payment models—for which we have issued waivers of the prohibitions of the physician self-referral law—the physician self-referral law prohibits financial relationships necessary to achieve the clinical and financial

integration required for successful health care delivery and payment reform. These concerns apply equally to the participation of physicians and entities furnishing health care services in models sponsored and paid for solely by non-federal payors, where care is provided solely to non-federal program patients, because the financial arrangements between the parties that result from participation in these models must satisfy the requirements of an applicable exception to the physician self-referral law in order to avoid the law's referral and billing prohibitions on DHS referred for and furnished to Medicare beneficiaries. We also have received numerous stakeholder inquiries, unrelated to participation in alternative health care delivery or payment models, regarding whether certain compensation methodologies would be viewed as taking into account the volume or value of a physician's referrals or other business generated between the physician and the entity furnishing DHS that provides the compensation. Many of these inquiries relate to performance-based or incentive compensation. We have not issued any formal guidance to date, either through a binding advisory opinion or rulemaking.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), enacted April 16, 2015, includes certain Medicare program integrity and fraud and abuse provisions. Notably, MACRA requires the Secretary to undertake two studies relating to the promotion of alternative payment models and to provide the Congress with a gainsharing study and report.

Section 101(e)(7) of MACRA requires the Secretary, in consultation with the Office of Inspector General (OIG), to study and report to the Congress on fraud related to alternative payment models under the Medicare program (the APM Report). The Secretary must study the applicability of the federal fraud prevention laws to items and services furnished under title XVIII of the Act for which payment is made under an alternative payment model, identify aspects of alternative payment models that are vulnerable to fraudulent activity, and examine the implications of waivers to the fraud prevention laws to support alternative payment models. The Secretary must include in the APM Report the results of her study and recommendations for actions to reduce the vulnerabilities of Medicare alternative payment models, including possible changes in federal fraud prevention laws to reduce such vulnerabilities. This report must be issued no later than 2 years after the enactment of MACRA.

Section 512(b) of MACRA requires the Secretary, in consultation with OIG, to submit to the Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that would otherwise be subject civil money penalties in paragraphs (1) and (2) of section 1128A(b) of the Act and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report). The Gainsharing Report must address whether the recommended changes should apply to ownership interests, compensation arrangements, or other relationships. The Gainsharing Report must also describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care. Further, the Secretary's Gainsharing Report must consider whether a portion of any savings generated by such arrangements should accrue to the Medicare program. This report must be issued no later than 12 months after the enactment of MACRA.

d. Solicitation of Comments

To inform the APM Report and Gainsharing Report required under sections 101(e)(7) and 512(b) of MACRA, respectively, as well as to aid us in determining whether additional rulemaking or guidance is desirable or necessary, we are soliciting comments regarding the impact of the physician self-referral law on health care delivery and payment reform. We are interested in comments regarding perceived barriers to achieving clinical and financial integration posed by the physician self-referral law generally and, in particular, the ''volume or value'' and ''other business generated'' standards set out in our regulations. We are also interested in learning whether stakeholders see a need for guidance on the application of our regulations as they relate to physician compensation that is unrelated to participation in alternative payment models. On this subject, we specifically solicit comments regarding the ''volume or value'' and ''other business generated'' standards, but welcome comments regarding any of our rules for determining physician compensation. To encourage robust commentary from stakeholders, we pose the following topics and questions for discussion:

- Does the physician self-referral law generally and, in particular, the ''volume or value'' and ''other business generated'' standards set out in our regulations, pose barriers to or limitations on achieving clinical and financial integration? If so, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?
- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception at § 411.355(b), which protects referrals for certain services performed by physician practices that meet the requirements of § 411.352)? Would legislative action be necessary to establish exceptions to support alternative payment models?
- Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?
- Is there need for new exceptions to the physician self-referral law to support shared savings or ''gainsharing'' arrangements? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or ''gainsharing'' arrangements?
- Should certain entities, such as those considered to provide high-value care to our beneficiaries, be permitted to compensate physicians in ways that other entities may not? For example, should we permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus

compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should we impose to protect against program and patient abuse? How should we define ''high-value care'' or ''high-value entity''? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?

- Could existing exceptions, such as the exception at § 411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor? If so, what conditions should we impose to protect against program and patient abuse from the compensation arrangements resulting from participation in such models?
- Have litigation and judicial rulings on issues such as compensation methodologies, fair market value, or commercial reasonableness) generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions? We are particularly interested in the need for guidance in the context of delivery system reform.
- Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at § 411.357(p) for indirect compensation arrangements?
- Given the changing incentives for health care providers under delivery system reform, should we deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should we impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his referrals to or other business generated for the entity paying the compensation? Should we apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high value care to our beneficiaries?

10. Technical Corrections

We have become aware that some of the manual citations listed in our regulations are no longer correct. We therefore propose to update regulations at § 411.351, definitions of ''entity'', '''incident to' services or services 'incident to''', ''parenteral and enteral nutrients, equipment, and supplies'', and ''physician in the group practice'', with the correct citations. We also propose to modernize the regulatory text by changing ''Web site'' to ''Web site'' in § 411.351, definition of ''list of CPT/HCPCS Codes'', § 411.357(k)(2), § 411.357(m)(2) through (m)(3), § 411.357(m)(5), § 411.362(c)(2)(iv) through (c)(2)(iv)(v), § 411.362(c)(5), and § 411.384(b). Lastly, we are removing the hyphen from ''publicly-traded'' in § 411.356(a) and § 411.361(d), and we are correcting a minor typographical error in § 411.357(p)(1)(ii)(A).

O. Private Contracting/Opt-Out

1. Background

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare. For those physicians and practitioners who opt out of Medicare in accordance with section 1802(b) of the Act, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act do not apply. As a result, if the conditions necessary for an effective opt-out are met, physicians and practitioners are permitted to privately contract with Medicare beneficiaries and to charge them without regard to Medicare's limiting charge rules.

a. Provisions of the Proposed Regulation

The private contracting/opt out law at section 1802(b) of the Act was recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Public Law 114–10). Prior to the MACRA amendments, the law specified that physicians and practitioners may opt out for a 2 year period. Individuals that wished to renew their opt-out at the end of a 2 year opt-out period were required to file new affidavits with their Medicare Administrative contractors (MAC). Section 106(a) of MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Therefore, physicians and practitioners that file opt-out affidavits on or after June 16, 2015 will no longer be required to file renewal affidavits in order to continue their opt-out status. The amendments further provide that physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2 year opt-out period may cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2 year opt-out period.

We propose to revise the regulations governing the requirements and procedures for private contracts at 42 CFR part 405, subpart D so that they conform with these statutory changes. Specifically, we propose to revise the following:

- The definition of ''Opt-out period'' at § 405.400 so that opt-out affidavits automatically renew unless the physician or practitioner properly cancels opt-out.
- Sections 405.405(b), 405.410(c)(1) and (2), 405.415(h), (m), and (o), 405.425, 405.435(a)(4), 405.435(b)(8), 405.435(d), and 405.445(b)(2) so those sections conform with the revised definition of ''Opt-out period''.
- Section 405.445(a) so that proper cancellation of opt-out requires a physician or practitioner to submit written notice, not later than 30 days before the end of the current 2-year opt-out period, that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.
- Section 405.450(a) so that failure to properly cancel opt-out is included as an initial determination for purposes of § 498.3(b).

To update the terminology in our regulations, we also propose to amend sections 405.410(d), 405.435(d), and 405.445(b)(2) so that the term ''carrier'' is replaced with ''Medicare Administrative contractor''.

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, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 37 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 37—ESTIMATED HOURLY WAGES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43–3021	17.10	*9.58	26.68
Business Operations Specialists	13–1000	33.69	33.69	67.38
Computer Systems Analysts	15–1121	41.98	41.98	83.96
Medical and Health Services Managers	11–9111	49.84	49.84	99.68
Medical Secretaries	43–6013	16.12	16.12	32.24
Physicians and Surgeons	29–1060	93.71	93.71	187.48

*For fringe benefits, we are using the December 2014 Employer Costs for Employee Compensation (*http://www.bls.gov/news.release/archives/ecec_03112015.pdf*).

Except where noted, 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)

1. ICRs Regarding 42 CFR Part 405, Subpart D

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Previously, physicians and practitioners wanting to renew their opt-out were required to file new valid affidavits with their Medicare Administrative Contractors (MAC).

To be consistent with section 106(a), we propose to revise 42 CFR part 405, subpart D governing the submission of opt-out affidavits. We estimate that 150 physicians/practitioners will submit new affidavits at 2 hr per submission or 300 hr (total). Previously, we estimated that 600 physicians/practitioners would submit renewal affidavits at 2 hr per submission or 1,200 hr (total). In this regard, the burden will decrease by −900 hr (300 hr − 1,200 hr) when physicians and practitioners no longer need to submit renewal affidavits starting on June 16, 2017. We also estimate that a Medical Secretary will perform this duty at $32.24/hr for a savings of −$29,016 (−900 hr × $32.24/hr).

Under § 405.445(a), physicians and practitioners that file valid opt-out affidavits on or after June 16, 2015 and do not want to extend their opt-out status at the end of a 2 year opt-out period may cancel by notifying us at least 30 days prior to the start of the next 2 year opt-out period. The burden associated with this new requirement is the time to draft, sign and submit the writing to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 minutes each for a total of 10 burden hours. We also estimate that a Medical Secretary will perform this duty at $32.24/hr for a cost of $322.40 (10 hr × $32.24/hr).

The requirements and burden will be submitted to OMB under control number 0938–0730 (CMS–R–234).

2. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462) and What Constitutes a Visit (§ 405.2463)

In §§ 405.2462(d) and 405.2463(c)(4), we propose that clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, may seek to become certified as grandfathered tribal FQHCs. To become certified, an eligible tribe or tribal organization must submit an enrollment application (CMS–855A, OMB control number 0938–0685) and all required accompanied documentation, including an attestation of compliance with the Medicare FQHC Conditions for Coverage at part 491, to the Jurisdiction H Medicare Administrative Contractor (A/B MAC).

We estimate that between 3 and 5 grandfathered tribal clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, would seek to become certified as grandfathered tribal FQHCs. Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

3. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462)

In § 405.2462(g)(3), we propose that RHCs must report Healthcare Common Procedure Coding System (HCPCS) and other codes as required in reporting services furnished to a Medicare beneficiary during a RHC visit effective for dates of service on or after January 1, 2016.

The ongoing burden associated with the requirements under § 405.2462(g)(3) is the time and effort it would take each of the approximately 4,000 Medicare certified RHCs to report the services furnished to a Medicare beneficiary during a RHC visit using HCPCS and other codes as required. We believe that most RHCs are already familiar with the use of HCPCS coding since RHCs typically record HCPCS coding through their billing software or electronic health record systems and they could be subject to HCPCS reporting in accordance with the National Uniform Billing Committee and Accredited Standards Committee X12 standards. In our estimates below, we do not disregard any RHCs that may already be reporting HCPCS coding but we do take into the account the range of time it will take for inexperienced RHCs compared to experienced RHCs. We recognize some RHCs may need to make minor updates in their systems, but more so, RHC billing staff will need education in HCPCS coding associated with Medicare payable RHC visits. Due to the scope of services payable as a RHC visit, we do not anticipate RHCs will face a significant burden in training and education of billing staff. We plan to

provide educational information on how RHCs are to report HCPCS and other codes as required and clarify other appropriate RHC billing procedures through sub-regulatory guidance.

We estimate that it will take 2 to 5 additional minutes to report HCPCS codes on RHC claims to Medicare and, for most RHCs, we believe that billing staff will require closer to 2 min when the RHCs become more experienced with including HCPCS coding on Medicare claims. As noted previously, for some RHCs, this requirement may not require any additional coding time since they already could be capturing HCPCS coding in their billing or electronic health record systems. Whereas, other RHCs may need up to 5 additional minutes to include HCPCS coding on Medicare claims. In this regard, we estimate a median of 3.5 additional minutes in the following calculations:

(8,964,208 Medicare claims in 2013 × 3.5 min)/60 min = 522,912.13 hr (aggregate)
522,912.13 hr/4,000 RHCs = 130.73 hr (per RHC)
522,912.13 hr × $26.68/hr = $13,951,295.63 additional cost (aggregate)
$13,951,295.63/4,000 RHCs = $3,487.82 per RHC

In deriving these figures, we analyzed claims data and RHC certification data maintained by CMS. We also used wage data from the Bureau of Labor Statistics (see Table 37).

The burden for the aforementioned requirements will be submitted to OMB for approval under control number 0938–New (CMS–10568).

4. ICRs Regarding Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Section 411.357 would be revised to establish two new exceptions: An exception to permit remuneration to independent physicians to assist in employing nonphysician practitioners in the geographic service area of the hospital, FQHC, or RHC providing the remuneration; and an exception to permit timeshare arrangements for the use of premises, equipment, personnel, items, supplies or services. Arrangements covered by these new exceptions must be in writing. We have also proposed clarifications to the writing requirements for compensation arrangements in § 411.357(a), (b), (d), (e), (l), (p), and (r). The burden associated with these requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties.

While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

5. ICRs Regarding [the] Physician Quality Reporting System (PQRS) (§ 414.90 and Section K of This Preamble)

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals and group practices identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option. We assume that most eligible professionals participating in the PQRS will attempt to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least nine measures covering at least three National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment, we will assume that each eligible professional reports on an average of nine measures for this burden analysis.

For eligible professionals who are participating in PQRS, we estimate that it will take 5 hr for an eligible professional's billing clerk to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hr to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes that 3 hours is sufficient time for an eligible professional to review the measure specifications of nine measures or one measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures groups into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hr × $26.68/hr = $133.40.

We continue to expect the ongoing cost associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

The proposed requirements and burden estimates will be submitted to OMB under control number 0938–1059 (CMS–10276).

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Claims-Based Reporting Mechanism

Under the claims-based reporting option, eligible professionals must

gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved under OMB control number 0938–0999. This rule does not propose any changes to these forms. Beginning in 2014, CMS made changes on how Critical access hospitals (CAHs) were billed under Medicare which made it possible for eligible professionals in CAH method II payment to participate in PQRS.

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for nine measures) would range from 15 sec (0.25 min) to over 12 min for complicated cases and/or measures, with the median time being 1.75 min. To report nine measures, we estimate that it would take approximately 2.25 min (0.25 min × 9) to 108 min (12 min × 9) to perform all the steps necessary to report nine measures.

At an adjusted labor rate of $83.96/hr for a computer systems analyst, the per measure cost would range from $0.35 [($83.96/hr/60) × 0.25 min] to $16.79 [($83.96/hr/60) × 12 min], with a median cost of $2.45 [($83.96/hr/60) × 1.75 min]. To report nine measures we estimate that the cost would range from *$3.15* ($0.35 × 9) to *$151.11* ($16.79 × 9), with a median cost of *$22.05* ($2.45 × 9).

The total estimated annual burden will vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting we found that, on average, the median number of reporting instances for each of the PQRS measures was nine. Since we reduced the required reporting rate by over one-third to 50 percent, we assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for six reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). For the 2018 payment adjustment, eligible professionals will also report on one cross-cutting measure if they see at least one Medicare patient. However, we do not see any additional burden impact as they are still reporting on the same number of measures.

Based on these assumptions, we estimate that the per individual eligible professional reporting burden would range from 13.5 min (0.25 min per measure × 9 measures × 6 cases per measure) to 648 min (12 min per measure × 9 measures × 6 cases per measure), with a median burden of 94.5 min (1.75 min per measure × 9 measures × 6 cases). We also estimate that the cost would range from *$18.90* [13.5 min ($83.96/hr/60)] to *$906.66* [648 min ($83.96/hr/60)], with a median cost of *$132.30* [94.5 min ($83.96/hr/60)].

Based on the assumptions discussed above, Table 38 provides an estimate of the range of total annual burden associated with eligible professionals using the claims-based reporting mechanism.

TABLE 38—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS USING THE CLAIMS-BASED REPORTING MECHANISM

	Minimum burden estimate	Median burden estimate	Maximum burden estimate
Estimated # of Participating Eligible Professionals (a)	350,000	350,000	350,000
Estimated # of Measures Per Eligible Professional Per Year (b)	9	9	9
Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)	6	6	6
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	54	54	54
Estimated Burden Hours Per Case (e)	0.00415	0.02917	0.19992
Estimated Total Burden Hours For Measures Per Eligible Professional Per Year (f) = (d)*(e)	0.2241	1.57518	10.79568
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (g)	5	5	5
Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f) + (g)	5.2241	6.57518	15.79568
Estimated Total Annual Burden Hours (i) = (a)*(h)	1,828,435	2,301,313	5,528,488
Estimated Cost Per Case (j)	$0.35	$2.45	$16.79
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$18.90	$132.30	$906.66
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (l)	$133.40	$133.40	$133.40
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$152.30	$265.70	$1,040.06
Estimated Total Annual Burden Cost (n) = (a)*(m)	$53,305,000	$92,995,000	$364,021,000

b. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-Based and QCDR-Based Reporting Mechanisms

For qualified registry-based and QCDR-based reporting, there will be no additional time for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be re-packaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this requirement will be approximately 5 min per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above, Table 39 provides an estimate of the total annual burden hours and cost associated with eligible professionals using the qualified registry-based or QCDR-based reporting mechanism. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple

occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

TABLE 39—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP PRACTICE) USING THE QUALIFIED REGISTRY-BASED AND QCDR-BASED REPORTING MECHANISMS

	Burden estimate
Estimated # of Participating Eligible Professionals (a) ..	212,000
Estimated Burden Hours Per Eligible Professional to Authorize the Qualified registry or QCDR to Report on Eligible Professional's Behalf (b)	0.083
Estimated Burden Hours Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (c) ..	3
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (d)	5
Estimated Total Annual Burden Hours Per Eligible Professional (e) = (b) + (c) + (d)	8.083
Estimated Total Annual Burden Hours (f) = (a)*(e)	1,713,596
Estimated Cost Per Eligible Professional to Authorize Qualified registry or QCDR to Report on Eligible Professional's Behalf (g)	$6.97
Estimated Cost Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (h)	$251.88
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (i)	$133.40
Estimated Total Annual Cost Per Eligible Professional (j) = (g) + (h) + (i)	$392.25
Estimated Total Annual Burden Cost (k) = (a)*(j)	$83,157,000

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

Under this reporting mechanism the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hr, depending on the number of patients on which the eligible professional or group practice is submitting. We also believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

In this rule, we are proposing that group practices with 25 or more eligible professionals must report on CAHPS for PQRS (OMB control number 0938–1222, CMS–10450). Therefore, a group practice of 25 or more eligible professionals would be required to report six or more measures covering two domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden on group practices, as we consider reporting the CAHPS for PQRS survey as reporting three measures covering one domain.

Based on the assumptions discussed above, Table 40 provides an estimate of the total annual burden hours and cost associated with EHR-based reporting for individual eligible professionals or group practices. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the EHR product would perform this function on the eligible professional's behalf.

TABLE 40—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP PRACTICE) USING THE EHR-BASED REPORTING MECHANISM

	Burden estimate
Estimated # of Participating Eligible Professionals (a) ..	50,000
Estimated Burden Hours Per Eligible Professional to Obtain IACS Account (b) ..	1
Estimated Burden Hours Per Eligible Professional to Submit Test Data File to CMS (c)	1
Estimated Burden Hours Per Eligible Professional to Submit PQRS Data File to CMS (d)	2
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (e)	5
Estimated Total Annual Burden Hours Per Eligible Professional (f) = (b) + (c) + (d) + (e)	9
Estimated Total Annual Burden Hours (g) = (a)*(f)	450,000
Estimated Cost Per Eligible Professional to Obtain IACS Account (h)	$83.96
Estimated Cost Per Eligible Professional to Submit PQRS Data File to CMS (includes 1hr for submitting test file, which is optional) (i)	$251.88
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (j)	$133.40
Estimated Total Annual Burden Cost Per Eligible Professional (k) = (h) + (i) + (j)	$469.24
Estimated Total Annual Burden Cost (m) = (a)*(k)	$23,462,000

d. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff

(billing and posting clerk). Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hr per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hr per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hr undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the self-nomination process has an adjusted labor rate of $26.68/hr. Therefore, assuming the time associated with the group practice self-nomination process is 6 hr per group practice, at a cost of $160.08 ($26.68/hr × 6 hr per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface is comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and are approved under OMB control number 0938–0941 (CMS–10136) for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hr to submit quality measures data via the GPRO web interface at a cost of $83.96/hr. Therefore, the annual cost is estimated at $6,632.84 per group practice.

Based on the assumptions discussed above, Table 41 provides an estimate of the total annual burden hours and cost associated with the group practice reporting of quality measures.

TABLE 41—SUMMARY OF BURDEN ESTIMATES FOR GROUP PRACTICES USING THE GPRO WEB INTERFACE REPORTING MECHANISM

	Burden estimate
Estimated # of Eligible Group Practices in 2013/2014 (a)	500
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (b)	6
Estimated # of Burden Hours Per Group Practice to Report (c)	79
Estimated Total Annual Burden Hours Per Group Practice (d) = (b) + (c)	85
Estimated Total Annual Burden Hours (e) = (a)*(d)	42,500
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (at a labor rate of $26.68/hr) (f)	$160.08
Estimated Cost Per Group Practice to Report (g)	$6,632.84
Estimated Total Annual Cost Per Group Practice (h) = (f) + (g)	$6,792.92
Estimated Total Annual Burden Cost (i) = (a)*(h)	$3,396,460

Please note that, beginning in 2013, we are requiring group practices that use the GPRO web interface reporting mechanism to administer a CAHPS survey. Please note that the burden estimates of implementing this survey is provided in a separate PRA package submission.

e. Total Estimated Burden of This Information Collection Requirement for 2013 and 2014

It is difficult to accurately estimate the total annual burden hours and costs associated with the submission of the quality measures data for the PQRS. For example, there are a number of reporting mechanisms available that eligible professionals can choose to use to report the PQRS measures. It may be more burdensome for some practices to use some reporting mechanisms to report the PQRS measures and/or electronic prescribing measure than others. This will vary with each practice. We have no way of determining which reporting mechanism an individual eligible professional will use in a given year, especially since EHR reporting and group practice reporting were new options for the 2010 PQRS and the QCDR option is new for the 2014 PQRS. Therefore, Table 42 provides a range of estimates for individual eligible professionals or group practices using the claims, qualified registry, or EHR-based reporting mechanisms. The lower range of the estimate assumes that eligible professionals will only participate in PQRS to avoid the PQRS payment adjustments that begin in 2015. The upper range assumes that eligible professionals participate in PQRS for purposes of earning an incentive as well as avoiding the PQRS payment adjustments. This upper range represents the sum of the estimated maximum hours and cost per eligible professional from Tables 37, 38, and 40. We are updating our previously approved estimates for the upper range of the estimates provided in Table 42.

TABLE 42—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS

	Minimum burden estimate	Maximum burden estimate
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	1,828,435	5,528,488
Estimated Annual Burden for Qualified Registry-based or QCDR-based Reporting	1,713,596	1,713,596
Estimated Annual Burden Hours for EHR-based Reporting	450,000	450,000
Estimated Total Annual Burden Hours for Eligible Professionals or Eligible Professionals in a Group Practice	3,992,031	7,692,084
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	$53,305,000	$364,021,000
Estimated Cost for Qualified Registry-based Reporting	$83,157,000	$83,157,000
Estimated Cost for EHR-based Reporting	$23,462,000	$23,462,000

TABLE 42—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS—Continued

	Minimum burden estimate	Maximum burden estimate
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	$159,924,000	$470,640,000

For purposes of estimating the reporting burden for group practices, Table 43 provides a summary of an estimate for group practices to participate in PQRS under the group practice reporting option using the GPRO web interface during 2015 (that is, Table 41).

TABLE 43—SUMMARY OF BURDEN ESTIMATES FOR GROUP PRACTICES USING THE GPRO WEB INTERFACE REPORTING MECHANISM

	Maximum burden estimate
Estimated # of Participating Group Practices	500
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report Quality Measures	79
Estimated Total Annual Burden Hours Per Group Practice	85
Estimated Total Annual Burden Hours for Group Practices	42,500
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	$160.08
Estimated Cost Per Group Practice to Report Quality Measures	$6,632.84
Estimated Total Annual Cost Per Group Practice	$6,792.12
Annual Burden Cost for Group Practices	$3,396,460

6. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of the statute (as amended by section 218(b) of the PAMA), CMS is proposing specific requirements for the development of appropriate use criteria (AUC) that can be specified under § 414.94 as part of the Medicare program. Provider-led organizations that use processes meeting certain requirements and want to be recognized as qualified provider-led entities for the purpose of this section may apply to CMS.

Applications must be submitted electronically and demonstrate how the organization's processes meet the requirements specified in § 414.94(c)(1) which include: A systematic literature review of the clinical topic and relevant imaging studies; AUC development led by at least one multidisciplinary team with autonomous governance; a process for identifying team members' conflicts of interest; publication of individual appropriate use criterion on each organizations Web site; identification of key decision points for individual criterion as evidence-based or consensus-based and strength of evidence grading per a formal, published, and widely recognized methodology; a transparent process for the timely and continual updating of each criterion; and a process for developing, modifying or endorsing AUC publicly posted on the entity's Web site.

To be identified as a qualified provider-led entity by CMS, organizations must demonstrate adherence to the requirements in their application and use the application process identified in § 414.94(c)(2) which includes: Only entities meeting the definition of provider-led entity are eligible to submit applications documenting adherence to each AUC development requirement; applications may be accepted annually by January 1; all approved provider-led entities will be posted to our Web site by June 30; and all qualified provider-led entities must re-apply every 6 years and applications must be submitted by January 1 during the 5th year of approval.

The one-time burden associated with the requirements under § 414.94(c)(2) is the time and effort it would take each of the 30 organizations that have expressed interests in developing AUC to compile, review and submit documentation demonstrating adherence to the proposed AUC development requirements. We anticipate 30 respondents based on the number of national professional medical specialty societies and other organizations that have expressed interest in participating in this program as well as other entities we have not heard from but would expect to participate.

We estimate it will take 20 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 5 hr at $187.48/hr for a physician to review and approve the submission materials. In this regard, we estimate 30 hr per submission at a cost of $2,783.40 per organization. In aggregate, we estimate 900 hr (30 hr × 30 submissions) at $83,502 ($2,783.40 × 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified provider-led entities annually. Since we estimate fewer than ten respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Qualified provider-led entities must re-apply every 6 years. Therefore in years 7–10, we expect that 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 provider-led entity will be able to make modifications to their original application which should result in a burden of 10 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hr at $187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hr per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hr (15 hr × 30 submissions) at $41,751 ($1,391.70 × 30 submissions).

The proposed requirements and burden will be submitted to OMB under control number 0938–New (CMS–10570).

7. ICRs Regarding the Comprehensive Primary Care (CPC) Initiative and the Medicare EHR Incentive Program (Section L of This Preamble)

Section L outlines an aligned reporting option between the Comprehensive Primary Care (CPC) initiative and the Medicare EHR Incentive Program whereby a practice site participating in CPC can report at least nine clinical quality measures as defined by the model that are across three domains and receive credit for reporting to the model as well as receive credit for the clinical quality measure reporting requirement of the Medicare EHR Incentive Program. While the reporting of quality measures is an information collection, the requirement is exempt from the PRA in accordance with section 1115A(d)(3) of the Social Security Act.

8. ICRs Regarding the Medicare Shared Savings Program (Section M of This Preamble)

While the proposed measures discussed in section M of this preamble is a collection of information, section 3022 of the Affordable Care Act exempts any collection of information associated with the Medicare Shared Savings Program from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Consequently, we are not setting out any burden for OMB approval.

C. Summary of Proposed Annual Burden Estimates

TABLE 44—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Section(s) in title 42 of the CFR	OMB No. (CMS ID No.)	Respondents	Responses (total)	Burden per response	Total annual burden (hr)	Labor rate for reporting ($/hr)	Total cost ($)
Part 405, subpart D	0938–0730 (CMS–R–234).	−450	−450	2 hr	−900	67.38	−60,642
405.445(a)	0938–0730 (CMS–R–234).	60	60	10 min	10	67.38	674
405.2462(g)(3)	0938–New (CMS–10568).	4,000	8,964,208	3.5 min	522,912.13	26.68	13,951,296
414.90 and section K of this preamble.	0938–1059 (CMS–10276).	350,000 (claims-based reporting).	54 (9 × 6)	5.2 hr (5 hr + 12 min).	5,528,488	varies (see Table 1).	364,021,000
		212,000 (qualified registry-based and QCDR-based reporting).	212,000	8.083 hr	1,713,596	varies (see Table 2).	83,157,000
		50,000 (EHR-based reporting).	50,000	9	450,000	varies (see Table 3).	23,462,000
		500 (GPRO web interface).	500	85	42,500	varies (see Table 4).	3,396,460
414.94(c)(1) and (2)	0938–New (CMS–10570).	30	30	5 hr	150	187.48	28,113
				5 hr	150	99.68	14,952
				20 hr	600	67.38	40,332
Total					8,257,506		488,011,185

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection 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/Paperwork@cms.hhs.gov,* 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–1631–P).

PRA-related comments must be received on/by September 8, 2015.

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 Part B payment policy and other Part B related policies.

B. Overall Impact

We have 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 below in this section, that the PFS provisions included in this proposed rule will 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 have prepared a 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 are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, 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 2015, that threshold is approximately $144 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 promulgates 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 have 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 revenues for PFS services compare payment rates for CY 2015 with proposed payment rates for CY 2016 using CY 2014 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). The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 established the update factor for calendar years 2015 through 2025. To calculate the conversion factor for the update year, we multiply the product of the current year conversion factor and the update factor by the budget neutrality adjustment. We estimate the CY 2016 PFS conversion factor to be $36.1096, which reflects a budget neutrality adjustment of 0.9999 and the 0.5 percent update factor specified under MACRA. We estimate the CY 2016 anesthesia conversion factor to be $22.6296, which reflects the 0.9999 budget neutrality adjustment, a 0.99602 anesthesia fee schedule adjustment practice expense and malpractice adjustment, and the 0.5 percent update specified under the MACRA. 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.

As we discuss in section II.F.4 of this proposed rule, because CY 2016 represents a transition year in our new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period, we will not be able to calculate a realistic estimate of the target amount at the time the proposed rule is published. Therefore, we did not incorporate the impact of the target into the calculation of the proposed conversion factor. However, we did estimate the net reduction in expenditures as a result of proposed adjustments to the relative value established for misvalued codes in this proposed rule, not including interim final changes that will be established in the CY 2016 PFS final rule. The net reduction is approximately 0.25 percent of the estimated amount of expenditures under the fee schedule for CY 2016.

Table 45 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 will be different from those shown in Table 45 (CY 2016 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 45.

- *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 2014 utilization and CY 2015 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 2016 impact on total allowed charges of the proposed 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 2016 impact on total allowed charges of the proposed changes in the PE RVUs.
- *Column E (Impact of RVU Changes):* This column shows the estimated CY 2016 impact on total allowed charges of the proposed 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 2016 combined impact on total allowed charges of all the proposed changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 45—CY 2016 PFS PROPOSED RULE 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	$88,408	0	0	0	0
ALLERGY/IMMUNOLOGY	220	0	1	0	1
ANESTHESIOLOGY	1,959	0	2	−2	0
AUDIOLOGIST	60	0	−1	1	−0
CARDIAC SURGERY	340	0	0	0	0
CARDIOLOGY	6,462	0	0	0	0
CHIROPRACTOR	781	0	0	0	0
CLINICAL PSYCHOLOGIST	713	0	0	0	0
CLINICAL SOCIAL WORKER	552	0	0	0	0
COLON AND RECTAL SURGERY	160	−1	0	−1	−1
CRITICAL CARE	293	0	0	0	0
DERMATOLOGY	3,207	0	0	0	1
DIAGNOSTIC TESTING FACILITY	719	0	1	0	1
EMERGENCY MEDICINE	3,099	0	0	0	0
ENDOCRINOLOGY	452	0	0	0	0
FAMILY PRACTICE	6,043	0	0	0	0
GASTROENTEROLOGY	1,829	−2	−1	−1	−5
GENERAL PRACTICE	471	0	0	0	0
GENERAL SURGERY	2,186	0	0	0	0
GERIATRICS	213	0	0	0	0
HAND SURGERY	169	0	1	0	1
HEMATOLOGY/ONCOLOGY	1,781	0	0	0	0
INDEPENDENT LABORATORY	823	1	8	0	9
INFECTIOUS DISEASE	655	0	0	0	0
INTERNAL MEDICINE	10,964	0	0	0	0
INTERVENTIONAL PAIN MGMT	715	0	1	0	1
INTERVENTIONAL RADIOLOGY	296	0	1	0	1
MULTISPECIALTY CLINIC/OTHER PHYS	95	0	0	0	0
NEPHROLOGY	2,187	0	0	0	0
NEUROLOGY	1,512	0	0	0	0
NEUROSURGERY	770	0	0	−1	−1
NUCLEAR MEDICINE	46	0	0	0	0

TABLE 45—CY 2016 PFS PROPOSED RULE 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)
NURSE ANES/ANES ASST	1,181	0	2	−2	0
NURSE PRACTITIONER	2,528	0	0	0	0
OBSTETRICS/GYNECOLOGY	664	0	0	0	0
OPHTHALMOLOGY	5,490	0	0	0	0
OPTOMETRY	1,167	0	0	0	0
ORAL/MAXILLOFACIAL SURGERY	45	0	0	0	0
ORTHOPEDIC SURGERY	3,653	0	0	0	0
OTHER	25	0	0	0	0
OTOLARNGOLOGY	1,195	0	−1	0	0
PATHOLOGY	1,316	4	4	0	8
PEDIATRICS	59	0	0	0	0
PHYSICAL MEDICINE	1,027	0	0	0	0
PHYSICAL/OCCUPATIONAL THERAPY	3,077	0	0	0	0
PHYSICIAN ASSISTANT	1,716	0	0	0	0
PLASTIC SURGERY	371	0	0	0	1
PODIATRY	1,978	0	0	0	0
PORTABLE X-RAY SUPPLIER	103	0	0	0	0
PSYCHIATRY	1,300	0	0	0	0
PULMONARY DISEASE	1,769	0	0	0	0
RADIATION ONCOLOGY	1,769	0	−3	0	−3
RADIATION THERAPY CENTERS	52	0	−9	0	−9
RADIOLOGY	4,472	0	0	0	0
RHEUMATOLOGY	534	0	0	0	0
THORACIC SURGERY	346	0	0	0	0
UROLOGY	1,789	0	0	0	0

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2016 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to two major factors. The first factor, as discussed in section II. of this proposed rule, is the number of changes to RVUs for specific services resulting from the Misvalued Code Initiative, including the establishment of RVUs for new and revised codes. Several specialties, including radiation therapy centers, radiation oncology, and gastroenterology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and the inputs used to develop RVUs for the codes that describe particular services. Other specialties, including pathology and independent laboratories, will experience significant increases to payments for similar reasons.

The second factor relates to a technical improvement that refines the MP RVU methodology, which we are proposing to make as part of our annual update of malpractice RVUs. This technical improvement will result in small negative impacts to the portion of PFS payments attributable to malpractice for gastroenterology, colon and rectal surgery, and neurosurgery.

b. Combined Impact

Column F of Table 45 displays the estimated CY 2016 combined impact on total allowed charges by specialty of all the proposed RVU changes. Table 46 (Impact of Proposed Rule on CY 2016 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the proposed changes. 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 found on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

TABLE 46—IMPACT OF PROPOSED RULE ON CY 2016 PAYMENT FOR SELECTED PROCEDURES

CPT/ HCPCS [1]	MOD	Short descriptor	Facility			Non Facility		
			CY 2015 [2]	CY 2016 [3]	% Change	CY 2015 [2]	CY 2016 [3]	% Change
11721		Debride nail 6 or more	$25.15	$25.64	2	$45.28	$46.22	2
17000		Destruct premalg lesion	53.90	54.88	2	67.20	68.24	2
27130		Total hip arthroplasty	1,407.87	1,411.02	0	NA	NA	NA
27244		Treat thigh fracture	1,277.80	1,285.37	1	NA	NA	NA
27447		Total knee arthroplasty	1,407.52	1,411.38	0	NA	NA	NA
33533		Cabg arterial single	1,952.63	1,963.08	1	NA	NA	NA
35301		Rechanneling of artery	1,203.41	1,204.14	0	NA	NA	NA

TABLE 46—IMPACT OF PROPOSED RULE ON CY 2016 PAYMENT FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS [1]	MOD	Short descriptor	Facility			Non Facility		
			CY 2015 [2]	CY 2016 [3]	% Change	CY 2015 [2]	CY 2016 [3]	% Change
43239		Egd biopsy single/multiple	154.15	152.72	−1	412.52	409.80	−1
66821		After cataract laser surgery	316.21	318.10	1	334.90	336.87	1
66984		Cataract surg w/iol 1 stage	650.40	646.65	−1	NA	NA	NA
67210		Treatment of retinal lesion	508.82	513.07	1	526.79	531.12	1
71010		Chest x-ray 1 view frontal	NA	NA	NA	22.64	22.75	0
71010	26	Chest x-ray 1 view frontal	9.34	9.39	1	9.34	9.39	1
77056		Mammogram both breasts	NA	NA	NA	116.42	117.35	1
77056	26	Mammogram both breasts	44.56	44.78	0	44.56	44.78	0
77057		Mammogram screening	NA	NA	NA	83.01	83.40	0
77057	26	Mammogram screening	35.93	36.11	0	35.93	36.11	0
77427		Radiation tx management x5	187.57	196.42	5	187.57	196.42	5
88305	26	Tissue exam by pathologist	39.17	39.72	1	39.17	39.72	1
90935		Hemodialysis one evaluation	73.66	74.01	0	NA	NA	NA
92012		Eye exam establish patient	53.18	53.79	1	86.24	86.65	0
92014		Eye exam&tx estab pt 1/>vst	80.85	81.24	0	124.69	125.65	1
93000		Electrocardiogram complete	NA	NA	NA	17.25	16.97	−2
93010		Electrocardiogram report	8.62	8.67	1	8.62	8.67	1
93015		Cardiovascular stress test	NA	NA	NA	77.26	76.54	−1
93307	26	Tte w/o doppler complete	45.99	46.22	0	45.99	46.22	0
93458	26	L hrt artery/ventricle angio	323.76	324.96	0	323.76	324.96	0
98941		Chiropract manj 3–4 regions	35.21	35.03	−1	41.32	41.53	0
99203		Office/outpatient visit new	77.98	78.35	0	109.60	110.12	0
99213		Office/outpatient visit est	51.38	51.99	1	73.30	74.01	1
99214		Office/outpatient visit est	79.41	79.43	0	108.88	109.04	0
99222		Initial hospital care	139.06	139.01	0	NA	NA	NA
99223		Initial hospital care	205.90	205.80	0	NA	NA	NA
99231		Subsequent hospital care	39.53	40.08	1	NA	NA	NA
99232		Subsequent hospital care	73.30	73.65	0	NA	NA	NA
99233		Subsequent hospital care	105.64	105.79	0	NA	NA	NA
99236		Observ/hosp same date	220.99	220.97	0	NA	NA	NA
99239		Hospital discharge day	108.88	109.04	0	NA	NA	NA
99283		Emergency dept visit	62.88	63.18	0	NA	NA	NA
99284		Emergency dept visit	119.66	119.87	0	NA	NA	NA
99291		Critical care first hour	227.46	227.83	0	279.20	279.82	0
99292		Critical care addl 30 min	113.55	114.10	0	124.33	125.29	1
99348		Home visit est patient	NA	NA	NA	84.80	85.57	1
99350		Home visit est patient	NA	NA	NA	178.95	180.17	1
G0008		Immunization admin	NA	NA	NA	25.51	25.64	0

[1] CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] Payments based on the 2015 conversion factor of 35.9335.
[3] Payments based on the estimated 2016 conversion factor of $36.1096.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.E. of this proposed rule, we are proposing 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 proposed additions.

E. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule

As discussed in section III.A.2 of this proposed rule, section 203 of the Medicare Access and CHIP Reauthorization Act of 2015 amended section 1834(l)(12)(A) and (l)(13)(A) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2017. These statutory ambulance extender provisions are self-implementing. As a result, there are no policy proposals associated with these provisions or associated impact in this rule. We are proposing only to correct the dates in the Code of Federal Regulations (CFR) at § 414.610(c)(1)(ii) and § 414.610(c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

For CY 2016 and subsequent CYs, we are proposing to continue implementation of the revised OMB delineations and the most recent modifications of the RUCA codes for purposes of payment under the ambulance fee schedule, as originally finalized and implemented in the CY 2015 PFS final rule with comment period as corrected (79 FR 67744 through 67750; 79 FR 78716 through 78719). The proposed continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs would mean the continued recognition of urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. For the RUCA codes, we would continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas. In addition, none of the super rural areas would lose their status based on our continued implementation of the revised OMB delineations and updated RUCA codes. As discussed in section III.A.3. of this proposed rule, the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs would continue to affect whether certain areas are designated as urban or rural, and whether or not transports would be

eligible for rural adjustments under the ambulance fee schedule statute and regulations. Descriptions of our proposals and accompanying rationale are set forth in more detail in section III.A.3. of this proposed rule. We estimate that our proposal to continue implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs would result in a minimal fiscal impact on the Medicare program as compared to CY 2015. We also estimate that our continued implementation of these geographic delineations would result in a minimal fiscal impact on ambulance providers and suppliers as compared to CY 2015, because we would be continuing implementation of the same revised OMB delineations and updated RUCA codes that were in effect in CY 2015. We note that there may be minimal impacts due to changes in ZIP codes based on updates by the USPS that we receive every two months.

As previously discussed in this section, most providers and suppliers, including ambulance companies, are small entities, either by their nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. Although, we do not believe that the proposed continued implementation of the revised OMB delineations and updated RUCA codes would have a significant economic impact on ambulance providers and suppliers as compared to CY 2015, we have included an analysis in section III.A.3. of this proposed rule describing certain impacts associated with implementation of these geographic delineations and have invited public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes. As further discussed in section III.A.3. of this proposed rule, Table 16 sets forth an analysis of the number of ZIP codes that changed urban and rural status in each U.S. state and territory after CY 2014 due to our implementation of the revised OMB delineations and updated RUCA codes, using an updated April 2015 USPS ZIP code file, the revised OMB delineations, and the updated RUCA codes (including the RUCA ZIP code approximation file discussed in that section).

In addition, we are proposing to revise § 410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished and the current Medicare requirements under § 410.41(b). In addition, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to include the proposed revised staffing requirements discussed in this section for § 410.41(b). Since we expect ambulance providers and suppliers are already in compliance with their state and local laws, we expect that this proposal would have a minimal impact on ambulance providers and suppliers. Similarly, we do not expect any significant impact on the Medicare program.

Furthermore, we are proposing to revise § 410.41(b) and the definition of BLS in § 414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified at a minimum as an EMT-Basic, which we believe would more clearly state our current policy. Also, for the reasons discussed in section III.A.4. of this proposed rule, we are proposing to delete the last sentence of our definition of BLS in § 414.605. Because these proposals do not change our current policies, we expect that they would have a minimal impact on ambulance providers and suppliers and do not expect any significant impact on the Medicare program.

2. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

As discussed in section III.B of this proposed rule, we are proposing to establish payment, beginning on January 1, 2016, for RHCs and FQHCs who 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 place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We also are proposing that payment for CCM be based on the 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.

In the CY 2015 PFS final rule (79 FR 67715 through 67730), we estimated that 65 percent of Medicare beneficiaries in fee-for-service practices had 2 or more chronic conditions, and that 30 percent of those beneficiaries would choose to receive CCM services. We also estimated that for those patients, there would be an average of 6 CCM billable payments per year.

We do not have the data to determine the percentage of Medicare beneficiaries in RHCs or FQHCs with 2 or more chronic conditions, but we have no reason to believe that the percentage would be different for patients in a RHC or FQHC. We also assume that the rate of acceptance, and the number of billable visits per year, would be the same for RHCs and FQHCs as it is for practitioners in non-RHC and FQHC settings that are billing under the PFS.

Based on these assumptions, we estimate that the 5-year cost impact of CCM payment in RHCs and FQHCs would be $ 850 million, of which $210 million is the premium offset and $640 million is the Part B payment. We estimate that the 10-year cost impact of CCM payment in RHCs and FQHCs would be $1.970 billion, of which $480 million is the premium offset and $1.490 billion is the Part B payment.

These estimates were derived by first multiplying the number of Medicare beneficiaries in RHCs and FQHCs per year by 0.65 percent, (the estimated percentage of Medicare beneficiaries with 2 or more chronic conditions). This number was then multiplied by 0.30 (the estimated percentage of Medicare beneficiaries with 2 or more chronic conditions that will choose to receive CCM services). This number was then multiplied by $42.91 (the national average payment rate per beneficiary per calendar month). Finally, this number was multiplied by 6 (the estimated number of CCM payments per beneficiary receiving CCM services). Table 47 provides the yearly estimates (figures are in millions):

TABLE 47—YEARLY ESTIMATES

[In millions]

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	5 Year impact 2016–2020	10 Year impact 2016–2025
FY Cash Impact—Part B: Benefits	$90	$170	$190	$200	$200	$210	$220	$220	$230	$230	$850	$1,970

TABLE 47—YEARLY ESTIMATES—Continued
[In millions]

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	5 Year impact 2016–2020	10 Year impact 2016–2025
Premium Offset	−20	−40	−50	−50	−50	−50	−50	−50	−50	−60	−210	−480
Total Part B	70	130	140	150	150	160	170	170	170	180	640	1,490

3. Healthcare Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

As discussed in section III.C. of this proposed rule, we are proposing to require HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. There will be no cost impact on the Medicare program since this proposal does not change the payment methodology for RHC services. This proposal would necessitate some RHCs to make changes to their billing practices; however, we estimate no significant cost impact on RHCs.

4. Payment to Grandfathered Tribal FQHCs That Were Provider-Based Clinics on or Before April 7, 2000

As discussed in section III.D. of this proposed rule, we are proposing that clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, may seek to become certified as grandfathered tribal FQHCs. We also propose that these grandfathered tribal FQHCs retain their Medicare outpatient per visit payment rate, as set annually by the IHS, rather than the FQHC PPS per visit base rate of $158.85. Since we are not proposing any changes to their payment rate, there will be no cost impact as a result of this proposal.

5. Part B Drugs—Payment for Biosimilar Biological Products Under Section 1847A

In section III.E. of this rule we discussed the payment of biosimilar biological products under section 1847A of the Act and proposed to clarify existing regulation text. The updated regulation text states that the payment amount for a biosimilar biological product is based on the average sales prices (ASP) of all NDCs assigned to the biosimilar biological products included within the same billing and payment code.

We anticipate that biosimilar biological products will have lower ASPs than the corresponding reference products, and we expect the Medicare Program will realize savings from the utilization of biosimilar biological products. However, at the time of writing this proposed rule, we have not yet received ASP data for any biosimilar biological products that have been approved under the FDA's biosimilar approval pathway. Further, it is not clear how many biosimilar products will be approved, when approval and marketing of various products will occur, what the market penetration of biosimilars in Medicare will be, and what the cost differences between the biosimilars as well as the price differences between the biosimilars and the reference products will be. Therefore, using available data, we are not able to quantify with certainty the potential savings to Medicare part B. Similarly, we are not able to quantify the impact, if any, on physician offices that administer biosimilar biological products.

6. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on Appropriate Use Criteria development process requirements as well as an application process that organizations must comply with to become qualified provider-led entities. These proposals would not impact CY 2016 physician payments under the PFS.

7. Oncology Care Model and Overlap With Care Management Services Under PFS

The participation requirements and financial incentives of the Oncology Care Model (OCM) are outlined in the model's Request for Applications (*http://innovation.cms.gov/initiatives/Oncology-Care/*) and in the model's announcement in the **Federal Register** on February 17, 2015 (80 FR 8323). The proposals for OCM set forth in the CY 2016 MPFS proposed rule articulate restrictions in OCM providers' ability to bill the model's Per-Beneficiary-Per-Month (PBPM) fee and for other MPFS care coordination services in the same month for the same beneficiary, given that the enhanced services required of each overlap in scope. Since the proposed policies are designed to limit the likelihood that Medicare double pays for similar services, these proposals are not expected to have a fiscal impact on the Medicare program.

8. Physician Compare

We do not estimate any impact as a result of the proposals for the Physician Compare Web site.

9. Physician Quality Reporting System

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Reporting in General

According to the 2013 Reporting Experience, ''more than 1.25 million eligible professionals were eligible to participate in the 2013 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model.'' [10] In this burden estimate, we assume that 1.25 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2013, will be eligible to participate in the PQRS. Since all eligible professionals are subject to the 2018 PQRS payment adjustment, we estimate 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.

Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. In the 2013 PQRS and eRx Reporting Experience Report more than 1.25 million professionals were eligible to participate in the 2013 PQRS (including group practices reporting under the GPRO, Medicare Shared Savings Program, and Pioneer ACO Model). Therefore, we believe that although 1.25 million eligible professionals will be subject to the 2018 PQRS payment adjustment, not all eligible participants will actually report quality measures data for purposes of the 2018 PQRS payment adjustment. In this burden estimate, we will only provide burden estimates for the eligible professionals and group

[10] Centers for Medicare and Medicaid Services, *2012 Reporting Experience Including Trends (2007–2013): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program,* March 14, 2014, at xiii.

practices who attempt to submit quality measures data for purposes of the 2018 PQRS payment adjustment.

In 2013, 641,654 eligible professionals (51 percent) eligible professionals (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the GPRO) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.[11] We expect to see a steady increase in participation in reporting for the PQRS in 2016 than 2013. Eligible professionals have become more familiar with the PQRS payment adjustments since eligible professionals are currently experiencing the implementation of the first PQRS payment adjustment—the 2015 PQRS payment adjustment. Therefore, we estimate that we will see a 70 percent participation rate in 2016. Therefore, we estimate that 70 percent of eligible professionals (or approximately 875,000 eligible professionals) will report quality measures data for purposes of the 2018 PQRS payment adjustment.

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals and group practices identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option. We assume that most eligible professionals participating in the PQRS will attempt to meet both the criteria for satisfactory reporting for the 2018 PQRS payment adjustment.

We believe the labor associated with eligible professionals and group practices reporting quality measures data in the PQRS is primarily handled by an eligible professional's or group practice's billing clerk or computer analyst trained to report quality measures data. Therefore, we will consider the hourly wage of a billing clerk and computer analyst in our estimates. For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the PQRS.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least 9 measures covering at least 3 National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment, we will assume that each eligible professional reports on an average of 9 measures for this burden analysis.

For eligible professionals who are participating in PQRS, we will assign 5 total hours as the amount of time needed for an eligible professional's billing clerk to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hours to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes 3 hours is plenty of time for an eligible professional to review the measure specifications of 9 measures or 1 measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures groups into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hr × $26.68/hr = $127.25.

We continue to expect the ongoing costs associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

b. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Claims-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, 229,282 of the 320,422 eligible professionals (or 72 percent) of eligible professionals used the claims-based reporting mechanism. According to the 2012 Reporting Experience, 248,206 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2012.[12] According to the 2013 PQRS and eRx Experience Report, 641,654 eligible professionals participated as individuals or group practices through one of the PQRS reporting mechanism, a 47 percent increase from those that participated in 2012 (435,931). Through the individual claims-based reporting mechanism, 331,668 of those eligible professionals (or 52 percent) reported using this mechanism. Increased claims based reporting to 350,000 (approximately 5 percent increase over 2013). Though claims reporting was declining, we did see an increase in 2013 once the payment adjustment was applied to all participants, so we assume a slight increase in 2016.

According to the historical data cited above, although the claims-based reporting mechanism is still the most widely-used reporting mechanism, we are seeing a decline in the use of the claims-based reporting mechanism in the PQRS. There was a slight increase in 2013, which may be reflected by the use of administrative claims-based reporting mechanism by individual eligible professionals and group practices only

[11] Id. at XV.

[12] Id. at xvi. *See* Figure 4.

for the 2015 PQRS payment adjustment (in CY2013).

Although these eligible professionals continue to participate in the PQRS, these eligible professionals have started to shift towards the use of other reporting mechanisms—mainly the GPRO web interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program), registry, or the EHR-based reporting mechanisms. For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we will assume that approximately 350,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism.

For the claims-based reporting option, eligible professionals must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures groups for which they can report the necessary information, incorporate reporting of the selected measures into the office work flows, and select a PQRS reporting option to be approximately *$419.80* per eligible professional ($83.96 per hour × 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all the steps necessary to report 9 measures.

Per measure, at an average labor cost of $83.96/hour per practice, the cost associated with this burden will range from $0.17 in labor to about $8.40 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.20. To report 9 measures, using an average labor cost of $42/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from *$3.15* (2.25 minutes or 0.0375 hours × $83.96/hour) to $151.13 (108 minutes or 1.8 hours × $83.96/hour) per reported case.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). For the 2018 payment adjustment, EPs will also report on 1 cross-cutting measure if they see at least 1 Medicare patient. However, we do not see any additional burden impact as they are still reporting on the same number of measures.

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-Based and Qualified Clinical Data Registry (QCDR)-Based Reporting Mechanisms

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. In 2012, 36,473 eligible professionals reported individual measures via the registry-based reporting mechanism, and 10,478 eligible professionals reporting measures groups via the registry-based reporting mechanism in 2012.[13] According to the 2013 Reporting Experience, approximately 67,896 eligible professionals participated in the PQRS using the registry-based reporting mechanism (51,473 for individual measures and 16,423 for measures groups). Please note that we currently have no data on participation in the PQRS via a Qualified Clinical Data Registry (QCDR), as 2014 is the first year in which an eligible professional may participate in the PQRS via a QCDR.

We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons:

- The PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures
- We believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves.

Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals to approximately 212,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2016. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

For qualified registry-based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be repackaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

For CY 2014, 90 qualified registries and 50 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS.[14] Therefore, a total of 140 entities are currently classified as qualified registries and/or QCDRs under the PQRS. Although we believe the number of qualified registries will remain the same in 2015,

[13] Id. at xvi. *See* Figure 4.

[14] The full list of qualified registries for 2014 is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014QualifiedRegistryVendors.pdf*.

we believe we will see a slight increase in the number of entities that become a QCDR in 2015. We estimate that an additional 10 entities (bringing the total number of QCDRs to 60 in 2015) will become QCDRs in 2015. We attribute this slight increase to entities that wish to become QCDRs but, for some reason (lack of information regarding the QCDR option, rejected during the qualification process, the inability to get its self-nomination info provided in time, etc.), were not selected to be QCDRs in 2014. Therefore, we estimate that a total of 150 entities will become qualified registries and/or QCDRs under the PQRS in 2015.

Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf will need to complete a self-nomination in order to be considered qualified to submit on behalf of eligible professionals or group practices unless the qualified registry or clinical data qualified registry was qualified to submit on behalf of eligible professionals or group practices for prior program years and did so successfully. We estimate that the self-nomination process for qualifying additional qualified registries or qualified clinical data registries to submit on behalf of eligible professionals or group practices for the PQRS will involve approximately 1 hour per qualified registry or qualified clinical data registry to draft the letter of intent for self-nomination.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as develop a measures flow and meet with CMS officials when additional information is needed. In addition, QCDRs must perform other functions, such as benchmarking and calculating their measure results. We note, however, that many of these capabilities may already be performed by QCDRs for purposes other than to submit data to CMS for the PQRS. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a qualified registry or QCDR will spend an additional 9 hours performing various other functions related to being a PQRS qualified entity.

We estimate that the staff involved in the qualified registry or QCDR self-nomination process will have an average labor cost of $83.96/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, we estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $839.60 ($83.96 per hour × 10 hours per qualified registry).

The burden associated with the qualified registry-based and QCDR reporting requirements of the PQRS will be the time and effort associated with the qualified registry calculating quality measures results from the data submitted to the qualified registry or QCDR by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants. We expect that the time needed for a qualified registry or QCDR to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures on their participants' behalf will vary along with the number of eligible professionals reporting data to the qualified registry or QCDR and the number of applicable measures. However, we believe that qualified registries and QCDRs already perform many of these activities for their participants. Therefore, there may not necessarily be a burden on a particular qualified registry or QCDR associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their participants. Whether there is any additional burden to the qualified registry or QCDR as a result of the qualified registry's or QCDR's participation in the PQRS will depend on the number of measures that the qualified registry or QCDR intends to report to CMS and how similar the qualified registry's measures are to CMS's PQRS measures.

In this proposed rule, we are proposing that group practices of 25 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 25 or more eligible professionals would be required to report on the CAHPS for PQRS, 6 or more measures covering 2 domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden to the group practices, as we consider reporting the CAHPS for PQRS survey as reporting 3 measures covering 1 domain.

d. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. In 2012 there was a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.[15] According to the 2013 PQRS and eRx Experience Report, 23,194 (3.6 percent) eligible professionals participating in PQRS used the EHR-based reporting mechanism.

As can be seen in the 2013 Experience Report, the number of eligible professionals and group practices using the EHR-based reporting mechanism are steadily increasing as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals will transition from using the claims-based to the EHR-based reporting mechanisms. To account for this anticipated increase, we continue to estimate that approximately 50,000 eligible professionals, whether participating as an individual or part of a group practice under the GPRO, would use the EHR-based reporting mechanism in CY 2016.

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

For EHR-based reporting for the PQRS, the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a

[15] Id. at XV.

CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hours, depending on the number of patients on which the eligible professional or group practice is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

In this proposed rule, we are proposing that group practices of 25 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 25 or more eligible professionals would be required to report on the CAHPS for PQRS, 6 or more measures covering 2 domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden to the group practices, as we consider reporting the CAHPS for PQRS survey as reporting 3 measures covering 1 domain.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the EHR product would perform this function on the eligible professional's behalf.

e. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

As noted in the 2011 Experience Report, approximately 200 group practices participated in the GPRO in 2011. According to the 2012 Reporting Experience, 66 practices participated in the PQRS GPRO.[16] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[17] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[18] According to the 2013 PQRS and eRx Experience Report, 677 group practices self-nominated to participate via the PQRS GPRO (compared to 68 total that self-nominated in 2012), 550 moved on to become PQRS group practices, another 220 practices were approved by CMS to participate as Medicare MSSP ACOs, and 23 were eligible under the Pioneer ACO model. The number of eligible professionals (from the 2013 Experience Report) participating in one of these reporting methods include: 131,690 in PQRS group practices, 21,678 in Pioneer ACO, and 85,059 in MSSP ACO. Group practices participating in PQRS GPRO are increasing each year, from roughly 200 group practices in 2011 and 2012, to 860 eligible practices in 2013 (including all GPRO, Pioneer ACO, and MSSP ACO. However, not all group practices use the Web Interface to report. We will assume, based on these numbers that 500 group practices (accounting for approximately 228,000 eligible professional) will continue to participate in the PQRS using the GPRO Web Interface in 2016.

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff. Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hours per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hours undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the group practice self-nomination process has an average practice labor cost of $26.68 per hour. Therefore, assuming the total burden hours per group practice associated with the group practice self-nomination process is 6 hours, we estimate the total cost to a group practice associated with the group practice self-nomination process to be approximately $160.08 ($26.68 per hour × 6 hours per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and was approved under OMB control number 0938–0941—Form 10136, with an expiration date of December 31, 2011 for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hours to submit quality measures data via the GPRO web interface at a cost of $83.96 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $6,632.84.

10. EHR Incentive Program

The changes to the EHR Incentive Program in section III.L of this proposed rule would not impact the current burden estimate for the EHR Incentive Program.

11. Comprehensive Primary Care (CPC) Initiative and Meaningful Use Aligned Reporting

The establishment of an aligned reporting option between CPC and the Medicare EHR Incentive Program does

[16] Id. at xv.

[17] Id. at xvi.

[18] Id. at 18.

not impact the CY 2016 payments under PFS.

12. Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

The solicitation of public input regarding potential CPC expansion does not impact CY2016 payments under the PFS, because no actual expansion is being proposed at this time.

13. Medicare Shared Saving Program

The requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule implementing the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67802). In this rule, we are proposing a change to the quality measure set. We are also proposing to establish rules for maintaining a measure as pay for reporting, or reverting a pay for performance measure to pay for reporting if a measure owner determines the measure no longer meets best clinical practices due to clinical guidelines updates or clinical evidence suggests that continued application of the measure may result in harm to patients. In addition, we are proposing to update the assignment methodology to include claims submitted by electing teaching amendment hospitals. Since the proposed policies are not expected to increase the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants or change the financial calculations, there is no impact for these proposals.

14. 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. Unless specified, the proposed changes to the VM in section III.N of this proposed rule would not impact CY 2016 physician payments under the PFS. We finalized the VM policies that would impact the CY 2016 physician payments under the PFS in the CY 2013 PFS final rule with comment period (77 FR 69306 through 69326) and the CY 2014 PFS final rule with comment period (78 FR 74764 through 74787).

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the VM by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals (EPs). We identify a group of physicians as a single taxpayer identification number (TIN). We apply the VM to the items and services billed by physicians under the TIN, not to other EPs that also may bill under the TIN. We established CY 2014 as the performance period for the VM that will be applied to payments during CY 2016 (77 FR 69314). We also finalized that we will not apply the VM in CYs 2015 and 2016 to any group of physicians that is participating in the Medicare Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative, or other similar Innovation Center or CMS initiatives (77 FR 69313).

In the CY 2014 PFS final rule with comment period (78 FR 74765–74770), we finalized a policy to apply the VM in CY 2016 to physicians in groups with 10 or more EPs. We also adopted a policy to categorize groups of physicians subject to the VM in CY 2016 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2016 VM into two categories. Category 1 includes groups of physicians that (a) meet the criteria for satisfactory reporting of data on PQRS quality measures through the GPRO for the CY 2016 PQRS payment adjustment or (b) do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, if the PQRS-qualified clinical data registry reporting mechanism is selected) must be met during the CY 2014 reporting period for the PQRS CY 2016 payment adjustment. For the CY 2016 VM, Category 2 includes those groups of physicians that are subject to the CY 2016 VM and do not fall within Category 1. For those groups of physicians in Category 2, the VM for CY 2016 is −2.0 percent.

In addition, for the CY 2016 VM, we adopted that quality-tiering, which is the method for evaluating performance on quality and cost measures for the VM, is mandatory for groups of physicians with 10 or more EPs. In CY 2016, groups of physicians with between 10 and 99 EPs would not be subjected to a downward payment adjustment (that is, they will either receive an upward or neutral adjustment) determined under the quality-tiering methodology, and groups of physicians with 100 or more EPs, however, would either receive upward, neutral, or downward adjustments under the quality-tiering methodology.

Under the quality-tiering approach, each group's quality and cost composites are 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 compare the group's quality of care composite classification with the cost composite classification to determine the VM adjustment for the CY 2016 payment adjustment period according to the amounts in Table 48.

TABLE 48—2016 VM AMOUNTS UNDER QUALITY-TIERING

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	*+1.0x	*+2.0x
Average Cost	−1.0%	+0.0%	*+1.0x
High Cost	−2.0%	−1.0%	+0.0%

*Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the downward payment adjustments in Table 48 for those groups in Category 1 with the −2.0 percent downward payment adjustments for groups of physicians 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). 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 2016 on physicians in groups with 10 or more EPs based on their performance in CY 2014. In the CY 2016 PFS final rule with comment period, we will present the actual number of groups of physicians that will be subject to the VM in CY 2016.

15. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section II.P of this proposed rule. Physicians and Designated Health Services (DHS) entities have been complying with the requirements set forth in the physician self-referral law for many years, specifically in regard to clinical laboratory services since 1992 and to referrals for all other DHS since 1995. The majority of our proposals would reduce burden by clarifying previous guidance. We believe these proposals would allow parties to determine with greater certainty whether their financial relationships comply with an exception.

We also proposed new exceptions and a new definition that would accommodate legitimate financial arrangements while continuing to protect against program and patient abuse:

- In section II.P.2.A of this proposed rule, we proposed a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to physicians to assist with the employment of a non-physician practitioner. This new exception would promote access to primary care services, a goal of the Secretary and the Affordable Care Act.
- In section II.P.2.B of this proposed rule, we described our proposal to revise the physician recruitment exception to add a new definition of the geographic area served by an FQHC or RHC. This proposal would provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception.
- In section II.P.7 of this proposed rule, we proposed a new exception that would protect timeshare arrangements that meet certain criteria. This proposal would help ensure beneficiary access to care, particularly in rural and underserved areas.

To the extent that the new exceptions and definition permit additional legitimate arrangements to comply with the law, this rule would reduce the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

- In section II.P.9.B of this proposed rule, we discussed our proposal that the physician-owned hospital baseline bona fide investment level and the bona fide investment level include direct and indirect ownership and investment interests held by a physician regardless of whether the physician refers patients to the hospital. We recognize that some physician-owned hospitals may have relied on earlier guidance that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline bona fide physician ownership level and that, if one or more of our proposals described in section II.P.9.B are finalized, may have revised bona fide investment levels that may exceed the baseline bona fide investment levels calculated under our current guidance. We seek public comment on the impact of our proposed regulatory and policy revisions on physician-owned hospitals and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with our proposed revisions.

16. Opt Out Change

We propose revising the regulations governing the requirements and procedures for private contracts at part 405, subpart D so that they conform with the statutory changes made by section 106(a) of the MACRA. We anticipate no or minimal impact as a result of these revisions.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

G. 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 the proposed changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

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 Table 46, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $109.60, which means that in CY 2015, a beneficiary would be responsible for 20 percent of this amount, or $21.92. Based on this proposed rule, using the estimated CY 2016 CF, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 46, is $110.13, which means that, in CY 2016, the proposed beneficiary coinsurance for this service would be $22.03.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 49 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2015 to CY 2016 based on the FY 2016 President's Budget baseline. Note that subsequent legislation changed the updates for 2016 from those shown in the 2016 President's Budget baseline.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2016 Annualized Monetized Transfers	Estimated increase in expenditures of $670 million for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES—Continued

Category	Transfers
CY 2016 Annualized Monetized Transfers	Estimated increase in payment of $473 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 50—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2016 Annualized Monetized Transfers of beneficiary cost coinsurance.	$100 million.
From Whom to Whom?	Federal Government to Beneficiaries.

I. 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, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, 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 405.400 is amended by revising the definition of ''Opt-out period'' to read as follows:

§ 405.400 Definitions

* * * * *

Opt-out period means, with respect to an affidavit that meets the requirements of § 405.420, a 2-year period beginning on the date the affidavit is signed, as specified by § 405.410(c)(1) or § 405.410(c)(2) as applicable, and each successive 2-year period unless the physician or practitioner properly cancels opt-out in accordance with § 405.445.

* * * * *

■ 3. Section 405.405 is amended by revising paragraph (b) to read as follows:

§ 405.405 General rules.

* * * * *

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts out of Medicare for the opt-out period described in § 405.400 unless the opt-out is terminated early according to § 405.445.

* * * * *

■ 4. Section 405.410 is amended by revising paragraphs (b), (c)(1), (c)(2), and (d) to read as follows:

§ 405.410 Conditions for properly opting-out of Medicare.

* * * * *

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare Administrative contractor with which he or she would file claims absent the opt-out.

(c) * * *

(1) The initial 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file the opt-out affidavit(s) as specified in the previous paragraph, the initial 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit, and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare Administrative contractors at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter, and the furnishing of any items or services to a Medicare

beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

■ 5. Section 405.415 is amended by revising paragraphs (h), (m), and (o) to read as follows:

§ 405.415 Requirements of the private contract.

* * * * *

(h) State the expected or known effective date and the expected or known expiration date of the current 2-year opt-out period.

* * * * *

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the current 2-year opt-out period.

* * * * *

(o) Be entered into for each 2-year opt-out period.

■ 6. Section 405.425 is amended by revising the introductory text to read as follows:

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart, the following results obtain during the opt-out period:

* * * * *

■ 7. Section 405.435 is amended by revising paragraphs (a)(4), (b)(8), and (d) to read as follows:

§ 405.435 Failure to maintain opt-out.

(a) * * *

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the current 2-year period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) * * *

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the current 2-year period expires.

* * * * *

(d) If a physician or practitioner demonstrates that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract) within 45 days of a notice from the Medicare Administrative contractor of a violation of paragraph (a) of this section, then the requirements of paragraphs (b)(1) through (8) of this section are not applicable. In situations where a violation of paragraph (a) of this section is not discovered by the Medicare Administrative contractor during the current 2-year period when the violation actually occurred, then the requirements of paragraphs (b)(1) through (8) of this section are applicable from the date that the first violation of paragraph (a) of this section occurred until the end of the 2-year period during which the violation occurred (unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the Medicare Administrative contractor that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (a) of this section. Good faith efforts include, but are not limited to, refunding any amounts collected in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract.

■ 8. Section 405.445 is amended by revising the section heading and paragraphs (a) and (b)(2) to read as follows:

§ 405.445 Properly cancel opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written request (that indicates the physician or practitioner does not want to extend the application of his or her affidavit for a subsequent 2-year period) with each Medicare contractor with which he or she would file claims absent completion of opt-out, provided the written requests are submitted not later than 30 days before the end of the previous 2-year period.

(b) * * *

(2) Notify all Medicare contractors, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the initial 2-year period.

* * * * *

■ 9. Section 405.450 is amended by revising paragraph (a) to read as follows:

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, failed to properly terminate opt-out, or failed to properly cancel opt-out is an initial determination for purposes of § 498.3(b) of this chapter.

* * * * *

■ 10. Section 405.2410 is amended by revising paragraph (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(b) * * *

(1) For RHCs that are authorized to bill on the basis of the reasonable cost system—

(i) A coinsurance amount that does not exceed 20 percent of the RHC's reasonable customary charge for the covered service; and

* * * * *

■ 11. Section 405.2415 is amended by revising the section heading to read as follows:

§ 405.2415 Incident to Services and direct supervision.

* * * * *

■ 12. Section § 405.2448 is amended by revising paragraph (a)(2) to read as follows:

§ 405.2448 Preventive primary services.

(a) * * *

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist or clinical social worker employed by or under contract with the FQHC.

* * * * *

■ 13. Section § 405.2462 is amended by—

■ a. Revising paragraph (a) introductory text, the heading of paragraph (b), and paragraphs (b)(1) and (c) introductory text.

■ b. Amending paragraph (b)(2) by removing the reference ''paragraphs (e)(1) and (2)'' and adding in its place the reference ''paragraphs (f)(1) and (2)''.

■ c. Redesignating paragraphs (d), (e), and (f) as paragraphs (e), (f), and (g), respectively.

■ d. Adding paragraph (d).

■ e.. Revising newly redesignated paragraphs (e)(1)(i) and (ii).

■ f. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* A RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

* * * * *

(b) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate for each

beneficiary visit for covered services. This rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS.

* * * * *

(c) *Payment to FQHCs that are authorized to bill under the PPS.* A FQHC that is authorized to bill under the PPS is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. Except as noted in paragraph (d) of this section, this rate is adjusted for the following:

* * * * *

(d) *Payment to grandfathered tribal FQHCs.* (1) A ''grandfathered tribal FQHC'' is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider-based department of an IHS hospital.

(2) A grandfathered tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS.

(3) The payment rate is not adjusted:

(i) By the FQHC Geographic Adjustment Factor;

(ii) For new patients, annual wellness visits, or initial preventive physical examinations; or

(iii) Annually by the Medicare Economic Index or a FQHC PPS market basket.

(4) The payment rate is adjusted annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(e) * * *

(1) * * *

(i) 80 percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS; or

(ii) 80 percent of the lesser of a grandfathered tribal FQHC's actual charge, or the outpatient rate for Medicare as set annually by the IHS for tribal FQHCs that are authorized to bill at this rate.

* * * * *

(g) * * *

(3) FQHCs, RHCs, whether or not exempt from electronic reporting under § 424.32(d)(3) of this subchapter, are required to submit HCPCS and other codes as required in reporting services furnished.

■ 14. Section 405.2463 is amended by revising paragraph (c)(4) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(c) * * *

(4) For FQHCs billing under the PPS, and grandfathered tribal FQHCs that are authorized to bill as a FQHC at the outpatient per visit rate for Medicare as set annually by the Indian Health Service—

* * * * *

■ 15. Section 405.2464 is amended by—

■ a. Revising the heading of paragraph (a), paragraphs (a)(1), (a)(2), and (a)(5), the heading of paragraph (b), and paragraph (b)(1).

■ b. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 405.2464 Payment rate.

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraph (c) of this section, a RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC services.

* * * * *

(5) The RHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Payment rate for FQHCs billing under the prospective payment system.* (1) Except as specified in paragraph (c) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

* * * * *

(c) *Payment for chronic care management services.* Payment to RHCs and FQHCs for qualified chronic care management services is at the physician fee schedule national average payment rate.

(d) *Determination of the payment rate for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* These rates are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

§ 405.2467 [Amended]

■ 16. Section 405.2467 is amended by removing paragraph (b) and redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

■ 17. Section 405.2469 is amended by revising paragraphs (a) and (b)(2) and adding paragraph (b)(3) to read as follows:

§ 405.2469 FQHC supplemental payments.

(a) *Eligibility for supplemental payments.* FQHCs under contract (directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive under one of the following:

(1) The PPS rate if the FQHC is authorized to bill under the PPS; or

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs.

(b) * * *

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(3) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC outpatient rate as set forth in this section under paragraph (a)(2) of this section, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 18. 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.

■ 19. Section 410.26 is amended by revising paragraphs (a)(1) and (b)(5) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare program or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(5) Services and supplies must be furnished under the direct supervision of the billing physician (or other billing practitioner) who is enrolled under Medicare Part B at the time the services are furnished. Services and supplies furnished incident to transitional care management and chronic care management services can be furnished under the general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff.

* * * * *

■ 20. Section 410.41 is amended by revising paragraph (b) to read as follows:

§ 410.41 Requirements for ambulance suppliers.

* * * * *

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

* * * * *

■ 21. Section 410.78 is amended by adding paragraph (b)(2)(ix) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(ix) A certified registered nurse anesthetist as described in § 410.69.

* * * * *

■ 22. Section 410.160 is amended by revising paragraph (b)(8) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(8) Beginning January 1, 2011, for a surgical service, and beginning January 1, 2015, for an anesthesia service, furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical or anesthesia service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical or anesthesia service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 23. The authority citation for part 414 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).

■ 24. Section 411.351 is amended by—

■ a. Amending the definition of ''Entity'' by revising paragraph (3).

■ b. Revising the definitions of '' 'Incident to' services or services 'incident to' '', ''List of CPT/HCPCS Codes'', and ''Locum tenens physician''.

■ c. Amending the definition of ''Parenteral and enteral nutrients, equipment, and supplies'' by revising paragraphs (1) and (2).

■ d. Revising the definition of ''Physician in the group practice''.

■ e. Amending the definition of ''Remuneration'' by revising paragraph (2).

The revisions read as follows:

§ 411.351 Definitions.

* * * * *

Entity * * *

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9, as amended or replaced from time to time.

* * * * *

''*Incident to*'' *services or services* ''*incident to*'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4 as amended or replaced from time to time.

* * * * *

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the **Federal Register**, and is posted on the CMS Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.*

Locum tenens physician (or substitute physician) is a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11, as amended or replaced from time to time.

* * * * *

Parenteral and enteral nutrients, equipment, and supplies * * *

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time.

* * * * *

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment

rules in § 424.80(b)(2) of this chapter (see also Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

* * * * *

Remuneration * * *

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

* * * * *

■ 25. Section 411.353 is amended by revising paragraphs (g)(1)(i) and (ii) to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) * * *

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in § 411.355, § 411.356 or § 411.357, except with respect to the signature requirement in § 411.357(a)(1), § 411.357(b)(1), § 411.357(d)(1)(i), § 411.357(e)(1)(i), § 411.357(e)(4)(i), § 411.357(l)(1), § 411.357(p)(2), § 411.357(q) (incorporating the requirement contained in § 1001.952(f)(4)), § 411.357(r)(2)(ii), § 411.357(t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), § 411.357(v)(7)(i), § 411.357(w)(7)(i), § 411.357(x)(1)(i), or § 411.357(y)(1); and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.

* * * * *

■ 26. Section 411.354 is amended by revising paragraphs (c)(3)(i), (d)(1), (d)(4) introductory text, (d)(4)(i), (d)(4)(iv)(A), and (d)(4)(v) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(c) * * *

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the ''parties to the arrangements'' are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who ''stands in the shoes'' of the physician organization as required under paragraphs (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

* * * * *

(d) * * *

(1) Compensation is considered ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

* * * * *

(4) A physician's compensation from a *bona fide* employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the arrangement.

* * * * *

(iv) * * *

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

* * * * *

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, arrangement for personal services, or contract.

■ 27. Section 411.356 is amended by revising paragraphs (a) introductory text and (a)(1)(i) and (ii), and adding paragraph (a)(1)(iii) to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

* * * * *

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) * * *

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and

trades are standardized and publicly transparent.

* * * * *

■ 28. Section 411.357 is amended by—

■ A. Revising paragraphs (a) introductory text, (a)(1) through (4), (a)(5) introductory text, (a)(6), (a)(7), (b)(1) through (3), (b)(4) introductory text, (b)(5), (b)(6), (c)(3), (d)(1)(iii), (d)(1)(iv), (d)(1)(vii), (e)(1)(iii), (e)(1)(iv), (e)(4)(i), (e)(4)(iv), (e)(6), (f)(2), (k)(2), (l) introductory text, (l)(1), (l)(2), (m)(1), (m)(2), (m)(3), (m)(5), (p)(1)(ii)(A), (p)(2), (r)(2)(iv), (r)(2)(v), (s)(1), (t)(2)(iv)(A).

■ B. Adding paragraphs (x) and (y).

The revisions and additions read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

* * * * *

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) * * *

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor).

(3) The term of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

* * * * *

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (b) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) * * *

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

* * * * *

(d) * * *

(1) * * *

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

* * * * *

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(4) * * *

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice.

* * * * *

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

* * * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health

clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. If the federally qualified health center or rural health clinic draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the ''geographic area served'' by the federally qualified health center or rural health clinic may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the federally qualified health center's or rural health clinic's patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) * * *

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

* * * * *

(k) * * *

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

* * * * *

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

* * * * *

(m) * * *

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m) of this section.

* * * * *

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

* * * * *

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

* * * * *

(r) * * *

(2) * * *

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(s) * * *

(1) The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in such entity's local community or service area, and the offer does not take into account

the volume or value of referrals or other business generated between the parties;

* * * * *

(t) * * *

(2) * * *

(iv) * * *

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

* * * * *

(x) *Assistance to employ a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to employ a nonphysician practitioner to provide patient care services, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed the lower of—

(*1*) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of employment; or

(*2*) An amount calculated by subtracting all receipts attributable to services furnished by the nonphysician practitioner from the actual salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician during a period not to exceed the first 2 consecutive years of employment; and

(B) Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by—

(*1*) The physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 3 years of becoming employed by the physician (or the physician organization in whose shoes the physician stands under § 411.354(c) of this subpart)—

(A) Practiced in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished services at the medical practice site located in the geographic area served by the hospital.

(vi) The nonphysician practitioner—

(A) Is a *bona fide* employee of the physician or the physician organization in whose shoes the physician stands under § 411.354(c) of this subpart; and

(B) Furnishes only primary care services to patients of the physician's practice.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital.

(viii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), ''nonphysician practitioner'' means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, or a certified nurse-midwife as defined in section 1861(gg) of the Act.

(4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(*2*) of this section, ''referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, ''geographic area served by the hospital'' has the meaning set forth in paragraph (e)(2) of this section.

(6)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided by a licensee to a licensor under an arrangement for the use of the licensor's premises, equipment, personnel, items, supplies or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The licensor is a hospital or physician organization.

(3) The licensed premises, equipment, personnel, items, supplies and services are used predominantly for the provision of evaluation and management services to patients.

(4) The licensed equipment is—

(i) Located in the office suite where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished by the physician at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the licensee's referral of patients to the licensor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the licensee while using the licensor's premises, equipment, personnel, items, supplies or services; or

(B) Per-unit of service license fees that are not time-based, to the extent that

such fees reflect services provided to patients referred by the licensor to the licensee.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

■ 29. Section 411.361 is amended by revising paragraph (d) to read as follows:

§ 411.361 Reporting requirements.

* * * * *

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at § 411.354(b) or any compensation arrangement, as defined at § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly traded securities and mutual funds.

* * * * *

■ 30. Section 411.362 is amended by—

■ a. Amending paragraph (a) by adding the definitions of ''Ownership or investment interest'' and ''Public advertising for the hospital'' in alphabetical order.

■ b. Revising paragraphs (b)(3)(ii)(C), (c)(2)(iv), (c)(2)(v), and (c)(5) introductory text.

The additions and revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Ownership or investment interest means for purposes of this section a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

* * * * *

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) * * *

(3) * * *

(ii) * * *

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: Social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

* * * * *

(c) * * *

(2) * * *

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

* * * * *

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

* * * * *

■ 31. Section 411.384 is amended by revising paragraph (b) to read as follows:

§ 411.384 Disclosing advisory opinions and supporting information.

* * * * *

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the CMS Web site.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 32. 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)).

■ 33. Section 414.90 is amended by—

■ a. Adding paragraphs (j)(8) and (j)(9).

■ b. Revising paragraphs (k) introductory text, and (k)(2).

■ c. Redesignating paragraphs (l)(4) and (l)(5) as (k)(4) and (l)(4), respectively.
■ d. Adding new paragraph (k)(5).

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(8) *Satisfactory reporting criteria for individual eligible professionals for the 2018 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via claims.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(*ii*) [Reserved]

(*2*) [Reserved]

(B) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable to the eligible professional, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) [Reserved]

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.

(9) *Satisfactory reporting criteria for group practices for the 2018 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2018 PQRS payment adjustment reporting period, for a group practice of 25 or more eligible professionals, report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the cross-cutting measure set. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 25 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all

CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set.

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 25 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a certified survey vendor in addition to the GPRO web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 25 or more eligible professionals who elect to use the GPRO web interface must administer the CAHPS for PQRS survey.

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals and group practices.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, or group practice must meet the criteria for satisfactory participation as specified in paragraph (k)(3) for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

* * * * *

(2) *Reporting mechanism.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

* * * * *

(5) *Satisfactory participation criteria for individual eligible professionals and group practices for the 2018 PQRS payment adjustment.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a QCDR for the 2018 PQRS payment adjustment must report information on quality measures identified by the QCDR in the following manner:

(i) For the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use.

(ii) [Reserved]

* * * * *

■ 34. Section 414.94 is added to Subpart B to read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) Section 1834(q)—Recognizing Appropriate Use Criteria for Certain Imaging Services.

(2) Section 1834(q)(1)—Program Established.

(3) Section 1834(q)(2)—Establishment of Applicable Appropriate Use Criteria.

(b) *Definitions.* As used in this section unless otherwise indicated—

Advanced diagnostic imaging service means an imaging service as defined in section 1834(e)(1)(B) of the Act.

Applicable imaging service means an advanced diagnostic imaging service (as defined in section 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.

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

Appropriate use criteria (AUC) means criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria must be evidence-based. AUC are a collection of individual appropriate use criteria. Individual criteria is information presented 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).

Furnishing professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who furnishes an applicable imaging service.

Ordering professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who orders an applicable imaging service.

Priority clinical areas means clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the

determination of outlier ordering professionals.

Provider-led entity means a national professional medical specialty society, or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare.

Specified applicable appropriate use criteria means AUC developed, modified or endorsed by a qualified provider-led entity.

(c) *Qualified provider-led entities.* Provider-led entities (PLEs) must follow appropriate, evidence-based processes for the development of AUC and demonstrate adherence to the requirements below to be qualified by CMS. AUC developed, modified or endorsed by qualified PLEs are specified applicable AUC. Qualified PLEs may develop AUC, modify AUC developed by another entity, or provide endorsement to AUC developed by other entities.

(1) *Requirements for developing, modifying or endorsing AUC.* All of the following requirements must be met:

(i) An evidentiary review process that includes:

(A) A systematic literature review of the clinical topic and relevant imaging studies; and

(B) An assessment of the evidence using a formal, published and widely recognized methodology for grading evidence. Consideration of relevant published consensus statements by professional medical specialty societies must be part of the evidence assessment.

(ii) At least one multidisciplinary team with autonomous governance, decision making and accountability for developing, modifying or endorsing AUC. At a minimum the team must be comprised of three members including one with expertise in the clinical topic related to the criterion and one with expertise in the imaging modality related to the criterion.

(iii) A publicly transparent process for identifying potential conflicts of interest of members on the multidisciplinary team. The following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the AUC publication of the related recommendation:

(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC. This may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(B) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(iv) Individual criteria must be published on the provider-led entity's Web site and include an identifying title, authors, and key references used to establish the evidence. If relevant to a CMS identified priority clinical area, such a statement must be included.

(v) Key points in individual criteria must be identified as evidence-based or consensus-based, and graded in terms of strength of evidence using a formal, published and widely recognized methodology.

(vi) The provider-led entity must have a transparent process for the timely and continual updating of each criterion.

(vii) The provider-led entity's process for developing, modifying or endorsing AUC is publicly posted on the entity's Web site.

(2) *Process to identify qualifying provider-led entities.* Provider-led entities must meet all of the following criteria:

(i) Provider-led entities must submit an application to CMS that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section;

(ii) Applications will be accepted by CMS only from provider-led entities that meet the definition in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved provider-led entities from each year of submissions will be posted to the CMS Web site by June 30; and

(v) Qualified provider-led entities are required to re-apply every 6 years. The application must be submitted by January 1 during the 5th year of their approval.

(d) *Identifying priority clinical areas.* (1) CMS must identify priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, volume variability of utilization, and strength of evidence for imaging services. We will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.

(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.

(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals (section 1834(q)(5) of the Act).

(e) *Identification of non-evidence based AUC.* (1) CMS will accept public comment to facilitate identification of individual or groupings of AUC that fall within a priority clinical area and are not evidence-based. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

■ 35. Section 414.605 is amended by revising the definition of ''Basic life support (BLS)'' to read as follows:

§ 414.605 Definitions.

* * * * *

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

* * * * *

§ 414.610 [Amended]

■ 36. In § 414.610, amend paragraphs (c)(1)(ii) introductory text and (c)(5)(ii), by removing the date ''March 31, 2015'' and adding in its place the date ''December 31, 2017''.

■ 37. Section 414.904 is amended by revising paragraph (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(j) *Biosimilar biological products.* Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4)

of the Act for the reference drug product (as defined in § 414.902).

■ 38. Section 414.1205 is amended by adding the definition of ''Certified registered nurse anesthetist (CRNA)'' and ''Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS)'' in alphabetical order to read as follows:

§ 414.1205 Definitions.

* * * * *

Certified registered nurse anesthetist (CRNA) has the same meaning given this term under section 1861(bb)(2) of the Act.

* * * * *

Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) have the same meanings given these terms under section 1861(aa)(5) of the Act.

* * * * *

■ 39. Section 414.1210 is amended by—

■ a. Revising paragraph (a)(4), (b)(2)(i)(B), (b)(2)(i)(C), (b)(2)(i)(D), (b)(3)(i), (b)(4) and (c).

■ b. Adding paragraphs (b)(2)(i)(E), (b)(2)(i)(F), (b)(3)(ii) and (b)(3)(iii).

The revisions and additions read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) * * *

(4) For the CY 2018 payment adjustment period, to nonphysician eligible professionals who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 2 or more eligible professionals and to physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) * * *

(2) * * *

(i) * * *

(B) 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.

(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 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 with 10 or more eligible professionals and equal to −2% for groups with two to nine eligible professionals and for 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 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 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals or +2x (rather than +1x) if 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 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 +3x (rather than +2x) if the group has 10 or more eligible professionals, +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals, or +2.0x (rather than +1.x) if a solo practitioner or group consisting of nonphysician eligible professionals.

(E) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period is determined as described under § 414.1210(b)(2), regardless of whether any eligible professionals in the group or the solo practitioner also participate in an Innovation Center model during the performance period.

(F) 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.

* * * * *

(3) * * *

(i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in the Pioneer ACO Model or CPC Initiative if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the Pioneer ACO Model or CPC Initiative in the performance period.

(4) *Application of the value-based payment modifier to participants in other similar Innovation Center models.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based

payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the similar model in the performance period.

(c) *Group size and composition determination.* (1) The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis, the group did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

(2) Beginning with the CY 2016 payment adjustment period, the size of a group during the applicable performance period will be determined by the lower number of eligible professionals as indicated by the PECOS-generated list or claims analysis.

(3) For the CY 2018 payment adjustment period, the composition of a group during the applicable performance period will be determined based on whether the group includes physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and/or other types of nonphysician eligible professionals as indicated by the PECOS-generated list or claims analysis.

■ 40. Section 414.1215 is amended by adding paragraph (d) to read as follows:

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

(d) The performance period is calendar year 2016 for value-based payment modifier adjustments made in the calendar year 2018 payment adjustment period.

■ 41. Section 414.1235 is amended by adding paragraphs (c)(4) and (c)(5) to read as follows:

§ 414.1235 Cost measures.

* * * * *

(c) * * *

(4) Beginning with the CY 2016 payment adjustment period, the cost measures of a group and solo practitioner subject to the value-based payment modifier are adjusted to account for the group's and solo practitioner's specialty mix, by computing the weighted average of the national specialty specific expected costs and comparing this to the group's actual risk adjusted costs. Each national specialty-specific expected cost is weighted by the proportion of Part B payments incurred by each specialty within the group.

(5) The national specialty-specific expected costs referenced in paragraph (c)(4) of this section are derived by calculating, for each specialty, the weighted average of the risk-adjusted costs computed across all groups, where the weight for each group is equal to the number of beneficiaries attributed to the group, times the number of eligible professionals in the group with the relevant specialty, times the proportion of eligible professionals in the group with the relevant specialty.

■ 42. Section 414.1250 is amended by revising paragraph (a) to read as follows:

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate. Beginning with the CY 2016 performance period, eCQMs reported via EHRs are excluded from the overall benchmark for quality of care measures and separate benchmarks are used for eCQMs. The eCQM benchmark is the national mean for the measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

* * * * *

■ 43. Section 414.1255 is amended by revising paragraph (b) and removing paragraph (c) to read as follows:

§ 414.1255 Benchmarks for cost measures.

* * * * *

(b) Beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups and solo practitioners that meet the minimum number of cases for that measure under § 414.1265(a). In calculating the national benchmark, groups and solo practitioners' performance rates are weighted by the number of beneficiaries used to calculate the group or solo practitioner's performance rate.

■ 44. Section 414.1265 is amended by adding paragraph (a)(2), and revising paragraph (b) to read as follows:

§ 414.1265 Reliability of measures.

* * * * *

(a) * * *

(2) Starting with the CY 2017 payment adjustment period, the Medicare Spending Per Beneficiary measure described at § 414.1235(a)(6) is an exception to this paragraph (a). In a performance period, if a group or a solo practitioner has fewer than 100 cases for this MSPB measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b)(1) For the CY 2015 payment adjustment period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the value-based payment modifier.

(2) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a quality composite score that is classified as ''average'' under § 414.1275(b)(1) if such group and solo practitioner do not have at least one quality measure that

meets the minimum number of cases under paragraph (a) of this section.

(3) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group and solo practitioner do not have at least one cost measure that meets the minimum number of cases under paragraph (a) of this section.

■ 45. Section 414.1270 is amended by removing paragraphs (b)(5) and (c)(5), and adding paragraph (d) to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(d) For the CY 2018 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group with two to nine eligible professionals and a solo practitioner, a downward payment adjustment of −4.0 percent will be applied to a group with 10 or more eligible professionals, and a downward payment adjustment of −2.0 percent will be applied to a group or solo practitioner consisting of nonphysician eligible professionals subject to the value-based payment modifier if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; or

(iii) Such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(2) For a group composed of 10 or more eligible professionals that is not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(i).

(3) For a group composed of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(ii).

(4) For a group and a solo practitioner consisting of nonphysician eligible professionals that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(iii).

(5) If at least 50 percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

■ 46. Section 414.1275 is amended by adding paragraphs (c)(4) and (d)(3) to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(c) * * *

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period:

(i) For physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 10 or more eligible professionals:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

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 Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(ii) For physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with two to nine eligible professionals and physician solo practitioners:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	−1.0%	+0.0%	+1.0x*
High Cost	−2.0%	−1.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(iii) For physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups that consist of nonphysician eligible professionals, and solo practitioners who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS CONSISTING OF NONPHYSICIAN ELIGIBLE PROFESSIONALS, AND SOLO PRACTITIONERS WHO ARE PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	+0.0%	+0.0%	+1.0x*
High Cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d) * * *

(3) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2018 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of +5x (rather than +4x) if the group has 10 or more eligible professionals, +3x (rather than +2x) if a solo practitioner or the group has two to nine eligible professionals, or +3x (rather than +2x) if a solo practitioner or group consisting of nonphysician eligible professionals; and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals, +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals, or +2x (rather than +1x) if a solo practitioner or group consisting of nonphysician eligible professionals.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 47. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 48. Section 425.20, as amended on June 9, 2015 (80 FR 32833) and effective on August 10, 2015, is further amended in the definition of ''Primary care services'' by—

■ a. Revising paragraph (2) introductory text.

■ b. Adding paragraph (2)(v).

■ c. Adding paragraph (4).

The revision and additions read as follows:

§ 425.20 Definitions.

* * * * *

Primary care services * * *

(2) For performance year 2016 as follows:

* * * * *

(v) G0463 for services furnished in ETA hospitals.

* * * * *

(4) For performance years 2017 and subsequent years as follows:

(i) 99201 through 99215.

(ii) 99304–99318 (excluding claims including the POS 31 modifier) and 99319–99340

(iii) 99341 through 99350.

(iv) 99495, 99496 and 99490.

(v) G0402 (the code for the Welcome to Medicare visit).

(vi) G0438 and G0439 (codes for the annual wellness visits).

(vii) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(viii) G0463 for services furnished in ETA hospitals.

■ 49. Section 425.102 is amended by—

■ a. Adding paragraph (a)(8).

■ b. In paragraph (b), removing the phrase ''eligible participate'' and adding in its place the phrase ''eligible to participate''.

The addition reads as follows:

§ 425.102 Eligible providers and suppliers.

(a) * * *

(8) Teaching hospitals that have elected under § 415.160 of this chapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

* * * * *

■ 50. Section 425.402, as amended on June 9, 2015 (80 FR 32841) and effective on August 10, 2015, is further amended by adding paragraph (d) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(d) When considering services furnished by ACO professionals in teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in the assignment methodology under paragraph (b) of this section, CMS uses an estimated amount based on the amounts payable under the physician fee schedule for similar services in the geographic location of the teaching hospital as a proxy for the amount of the allowed charges for the service.

■ 51. Section 425.502 is amended by adding paragraph (a)(5) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) * * *

(5) CMS reserves the right to redesignate a measure as pay for reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm.

* * * * *

§ 425.504 [Amended]

■ 52. In § 425.504—

■ a. Amend paragraph (a)(1) by removing the phrase ''their ACO provider/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ b. Amend paragraphs (b)(1) and (c)(1) by removing the phrase ''their ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ c. Amend paragraphs (a)(2)(ii), (b)(2)(ii), (b)(3) and (c)(3), by removing the phrase ''its ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ d. Amend paragraphs (a)(2)(i), (b)(2)(i), and (c)(2) by removing the phrase ''ACO providers/suppliers that are eligible professionals'' and adding in

its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ e. Amend paragraphs (a)(3), (a)(4), and (b)(4), by removing the phrase ''ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ f. Amend paragraph (b)(3) by removing the phrase ''each ACO supplier/provider who is an eligible professional'' and adding in its place the phrase ''each eligible professional who bills under the TIN of an ACO participant''.

■ g. Amend paragraph (c)(3) by removing the phrase ''each ACO provider/supplier who is an eligible professional'' and adding in its place the phrase ''each eligible professional who bills under the TIN of an ACO participant''.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 53. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 54. In § 495.4 the definition of ''Certified electronic health record technology (CEHRT)'', as proposed to be revised on March 30, 2015 (80 FR 16795), is proposed to be further amended by revising paragraphs (1)(ii)(C)(2) and (2)(iii)(B) to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(1) * * *

(ii) * * *

(C) * * *

(2) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (c)(3); or 45 CFR 170.315(c)(2), (c)(3)(i) and (c)(3)(ii); and can be electronically accepted by CMS if the provider is submitting electronically.

* * * * *

(2) * * *

(iii) * * *

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures under the 2015 Edition certification criteria 45 CFR 170.315(c)(2), (c)(3)(i) and (c)(3)(ii), and can be electronically accepted by CMS.

* * * * *

Dated: June 24, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 30, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–16875 Filed 7–8–15; 4:15 pm]

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