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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-1631-FC]

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: Final rule with comment period.

SUMMARY: This major final rule with comment period 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: Effective date: The provisions of this final rule with comment period are effective on January 1, 2016, except the definition of “ownership or investment interest” in §411.362(a), which has an effective date of January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 29, 2015. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-1631-FC. 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-FC,
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-FC,
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 issues related to pathology and ophthalmology services or any physician payment issues not identified below.

Abdihakim Abdi, (410) 786-4735, for issues related to portable X-ray transportation fees.

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

Lindsey Baldwin, (410) 786-1694, for issues related to valuation of moderate sedation and colonoscopy services.

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

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

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.

Geri Mondowney, (410) 786-4584, for issues related to geographic practice cost indices, malpractice RVUs, target, and phase-in provisions.

Chava Sheffield, (410) 786-2298, for issues related to the practice expense methodology, impacts, and conversion factor.

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

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

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

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.

Deborah Krauss, (410) 786-5264 and Alexandra Mugge, (410) 786-4457, 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-Comprehensive Primary Care (CPC) initiative and Medicare EHR Incentive Program aligned reporting.

Rabia Khan or Terri Postma, (410) 786-8084 or ACO@cms.hhs.gov, 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, or Matthew Edgar (410) 786-0698, for issues related to physician self-referral updates.

Christiane LaBonte, (410) 786-7234, for issues related to Comprehensive Primary Care (CPC) initiative.

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

SUPPLEMENTARY INFORMATION:

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

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.

Provisions open for comment: We will consider comments that are submitted as indicated above in the “Dates” and “Addresses” sections on the following subject areas discussed in this final rule with comment period: interim final work, practice expense (PE), and malpractice (MP) RVUs (including applicable work time, direct PE inputs, and MP crosswalks) for CY 2016; interim final new, revised, potentially misvalued HCPCS codes as indicated in the Preamble text and listed in Addendum C to this final rule with comment period; and the additions and deletions to the physician self-referral list of HCPCS/CPT codes found on tables 50 and 51.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, 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)
AWV	Annual wellness visit
BBA	Balanced Budget Act of 1997 (Pub. L. 105-33)
BBRA	[Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)
CAD	Coronary artery disease
CAH	Critical access hospital
CBSA	Core-Based Statistical Area

CCM	Chronic care management
CEHRT	Certified EHR technology
CF	Conversion factor
CG-CAHPS	Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS	Clinical Laboratory Fee Schedule
CNM	Certified nurse-midwife
CP	Clinical psychologist
CPC	Comprehensive Primary Care
CPEP	Clinical Practice Expert Panel
CPT	[Physicians] Current Procedural Terminology (<i>CPT codes, descriptions and other data only are copyright 2014 American Medical Association. All rights reserved.</i>)
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
IPPE	Initial preventive physical exam
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
ISO	Insurance service office
IT	Information technology
IWPUT	Intensity of work per unit of time
LCD	Local coverage determination
MA	Medicare Advantage
MAC	Medicare Administrative Contractor

MAP	Measure Applications Partnership
MAPCP	Multi-payer Advanced Primary Care Practice
MAV	Measure application validity [process]
MCP	Monthly capitation payment
MedPAC	Medicare Payment Advisory Commission
MEI	Medicare Economic Index
MFP	Multi-Factor Productivity
MIPPA	Medicare Improvements for Patients and Providers Act (Pub. L. 110-275)
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003)
MP	Malpractice
MPPR	Multiple procedure payment reduction
MRA	Magnetic resonance angiography
MRI	Magnetic resonance imaging
MSA	Metropolitan Statistical Areas
MSPB	Medicare Spending per Beneficiary
MU	Meaningful use
NCD	National coverage determination
NCQDIS	National Coalition of Quality Diagnostic Imaging Services
NP	Nurse practitioner
NPI	National Provider Identifier
NPP	Nonphysician practitioner
NQS	National Quality Strategy
OACT	CMS's Office of the Actuary
OBRA '89	Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239)

OBRA '90	Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101- 508)
OES	Occupational Employment Statistics
OMB	Office of Management and Budget
OPPS	Outpatient prospective payment system
OT	Occupational therapy
PA	Physician assistant
PAMA	Protecting Access to Medicare Act of 2014 (Pub. L. 113-93)
PC	Professional component
PCIP	Primary Care Incentive Payment
PE	Practice expense
PE/HR	Practice expense per hour
PEAC	Practice Expense Advisory Committee
PECOS	Provider Enrollment, Chain, and Ownership System
PFS	Physician Fee Schedule
PLI	Professional Liability Insurance
PMA	Premarket approval
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 Website

The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS website 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 Final Rule with Comment Period, refer to item CMS-1631-FC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS website identified above should contact Donta Henson at (410) 786-1947.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule with comment period, 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 final rule with comment period revises payment policies under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes are 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 final rule with comment period, 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 final rule with comment period includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Advance Care Planning.
- 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 Website.
- 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 changes in this final rule with comment period will 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 is larger for a few specialties.

We have determined that this major final rule with comment period is economically significant. For a detailed discussion of the economic impacts, see section VII. of this final rule with comment period.

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 final rule with comment period, 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.B.2. of this final rule with comment period.

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

2. Calculation of Payments Based on RVUs

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

We received several comments regarding GPCIs that are not within the scope of proposals in the CY 2016 PFS proposed rule. Many of these commenters requested adjustments to GPCI values for the Puerto Rico payment locality. These commenters contend that the data used to calculate GPCIs do not accurately reflect the cost of medical practice in Puerto Rico. We have addressed some of these issues in response to specific comments in prior rulemaking, such as the CY 2014 PFS final rule with comment period (78 FR 74380 through 74391), and will further take comments into account when we next propose to update GPCIs. However, we also note that we anticipate proposing updated GPCIs during CY 2017 rulemaking, and in the context of that update, we will consider the concerns expressed by commenters and others regarding the GPCIs for the Puerto Rico locality.

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

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

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to 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 specifies that the amount by which such reduced expenditures exceed the target for a given year shall be treated as a reduction in expenditures for the subsequent year for purposes of determining whether the target for the subsequent year has been met. The provision also specifies that an amount equal to the difference between the target and the estimated net reduction in expenditures, called the target recapture amount, shall not be taken into account

when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. The PAMA amendments originally made the target provisions applicable for CYs 2017 through 2020 and set the target for reduced expenditures at 0.5 percent of estimated expenditures under the PFS for each of those 4 years.

Subsequently, section 202 of the Achieving a Better Life Experience Act of 2014 (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 target provisions apply for CYs 2016, 2017, and 2018; and setting a 1 percent target for reduced expenditures for CY 2016 and a 0.5 percent target for CYs 2017 and 2018. The implementation of the target legislation is discussed in section II.E. of this final rule with comment period.

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

Section 218(a) of the PAMA added a new section 1834(p) of the Act. Section 1834(p) of the Act requires for certain computed tomography (CT) services 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). The CT services that are subject to the payment reduction are 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, that are 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 the amendments made by section 218(a) of the PAMA is discussed in section II.G. of this final rule with comment period.

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) Requiring that we establish a Merit-based Incentive Payment System (MIPS) under which MIPS eligible professionals (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive annual payment adjustments (increases or decreases) based on their performance in a prior period.

These and other MACRA provisions are discussions in various sections of this final rule with comment period. Please refer to the table of contents for the location of the various MACRA provision discussions.

II. Provisions of the Final Rule with Comment Period 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).

Comment: Several commenters requested that CMS include pharmacists as active qualified health care providers for purposes of calculating physician PE direct costs. The commenters stated that there are a number of ongoing Center for Medicare and Medicaid Innovation (CMMI) initiatives in which pharmacists are making substantial contributions to redesigning healthcare delivery and financing. The commenters insisted that pharmacists need to be included in the calculation of direct PE expenses as an element of the clinical labor variable relating to physician services, to ensure optimal medication therapy outcomes for beneficiaries, and the absence of these pharmacists negatively impacts the health care system.

Response: The direct PE input database contains the service-level costs in clinical labor based on the typical service furnished to Medicare beneficiaries. Commenters did not suggest that the labor costs of pharmacists are a typical resource cost in furnishing any particular physicians' service. When such costs are typically incurred in furnishing such services, we do not have any standing policies that would prohibit the inclusion of the costs in the direct PE input database used to develop PE RVUs for individual services, to the extent that inclusion of such costs would not lead to duplicative payments. Therefore, we welcome more detailed information regarding the typical clinical labor costs involving pharmacists for particular PFS services. We note, however, that in many of the CMMI initiatives, payment is provided for care management and care coordination services, including services provided by pharmacists. As such, we encourage commenters to provide information about the inclusion of additional clinical labor costs for specific services described by HCPCS codes for which payment is made under the PFS, as opposed to clinical labor costs that may be typical only under certain initiatives.

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 proposed 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 change is reflected in the “PE/HR” file available on the CMS website 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>.

Comment: One commenter expressed support for the new proposal to use a proxy PE per hour for interventional cardiology by crosswalking to the PE/HR for cardiology.

Response: We appreciate the commenter’s support and are finalizing the crosswalk as proposed.

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 final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

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

relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Next, we incorporated the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(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 proposed a technical improvement to step 2a of this calculation. In place of the step 2a calculation described above, we proposed 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. Although this 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 final rule with comment period reflect this refinement to the PE methodology.

We did not receive any comments on this proposed refinement of the methodology.

Therefore, we are finalizing this refinement as proposed.

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. Although 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 proposed 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 website reflect this refinement to the PE methodology.

Comment: We received several comments supporting this proposed refinement of the methodology. Several commenters also urged us to override the utilization data for low-volume codes using a recommended list of expected specialty or dominant specialty, consistent with our previous approach.

Response: We appreciate the support for the use of the 3-year average of claims utilization for purposes of determining the specialty mix for individual service. As we stated in our proposal, we believe that the 3-year average will mitigate the need to use dominant or expected specialty instead of the claims data. However, we also understand that the hypothesis will be tested as soon as a new year of claims data is incorporated into the PFS ratesetting methodology. Because we anticipate incorporating CY 2015 claims data for use in CY 2017 ratesetting, we believe that the proposed PE RVUs associated with the CY 2017 PFS proposed rule will provide the best opportunity to determine whether service-level overrides of claims data are necessary. Therefore, we are finalizing the policy as proposed for CY 2016 but will seek comment on the proposed CY 2017 PFS rates and whether or not the incorporation a new year of utilization data mitigates the need for service-level overrides. At that time, we would reconsider whether or not to use a claims-based approach (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE RVUs for low-volume codes.

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

For most services the indirect allocator is: $\text{indirect PE percentage} * (\text{direct PE RVUs}/\text{direct percentage}) + \text{work RVUs}$.

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: $\text{indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs}$.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: $\text{indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs}$.

(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%
66	Team Surgeons	33%	33%

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

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary.

However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work RVUs: The setup file contains the work RVUs from this final rule with comment period.

The following is a summary of the comments we received regarding PE RVU methodology.

Comment: We received several comments in response to our proposal to use the 3 most recent years of Medicare claims data to determine the specialty mix assigned to each code. All commenters broadly supported the proposal to use a 3-year average to increase stability of PE RVUs and mitigate code-level fluctuations. Some commenters, including the RUC, also stated that for codes which are very low volume in the Medicare population, the dominant specialty(ies) should be assigned. These commenters stressed that CMS should continue to utilize the expertise of the RUC when making these assignments.

Response: For services that are newly created or very low volume, we will continue to explore different methods to ensure the utilization of the most accurate specialty mix.

(7) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

$(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1-(1/((1 + \text{interest rate})^{\text{life of equipment}})))) + \text{maintenance})$

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.H.6.b of this final rule with comment period for a discussion of our 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. After reviewing the comments received, 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, 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 solicited comments 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 noted 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 noted 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.

Comment: Many commenters stated that the current 5 percent equipment maintenance factor does not account for expensive maintenance contracts on pieces of highly technical equipment. Most commenters were supportive of the idea of adding an item-specific maintenance variable for equipment costs, which they stated would likely increase the accuracy of the PE RVUs across the PFS. These commenters stated that specialty societies and other stakeholders should be allowed to provide documentation to CMS, as they currently do for pricing new supplies and equipment, to apply for an increase in maintenance costs. Other commenters requested that if a fixed maintenance factor remains in place, it should be increased from 5 percent to 10 percent. One commenter expressed concern that CMS would entertain making a change in this aspect of the equipment cost per minute formula based on a few invoices when a change would impact every service in the fee schedule. The commenter expressed concerns with the possibility that CMS might adopt a variable maintenance factor based on the submission of individual invoices. Another commenter stated that without a systematic data collection methodology for determining maintenance factors, they had concerns that any invoices CMS received might not accurately capture the true costs of equipment maintenance.

Although most commenters were supportive of adopting a variable maintenance factor for equipment items, commenters also stated that they were unaware of any publicly available data source containing this information. One commenter agreed that there is no comprehensive

data source for the maintenance information and therefore it would be difficult to implement a variable maintenance formula. Multiple other commenters concurred that they were unaware of any such public dataset. Several commenters encouraged CMS to work with stakeholders to define service contracts/maintenance contracts, collect data on their associated costs and update the equipment maintenance adjustment factor as necessary.

Response: We appreciate the submission of extensive comments regarding the subject of equipment maintenance factor. We agree with commenters that we do not believe the annual maintenance factor for all equipment is exactly 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. However, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor, we do not believe that we have sufficient information at present to adopt a variable maintenance factor for equipment cost per minute pricing. While we believe that these costs ideally should be incorporated into the PE methodology, we also have serious concerns about the problems that result from incorporating anecdotal data based solely on voluntarily submitted pricing information. In establishing prices for equipment and supplies, in many cases we have found that the submitted invoices often overstate the costs for individual items relative to publically available prices. We believe that the incentives related to voluntarily submitted limited invoices for maintenance costs would likely produce information subject to similar limitations. However, in contrast to prices, where we have identified no feasible alternative, our alternative for determining maintenance rates is a long-established default maintenance rate. We also note that the amount of costs for maintenance under the current methodology is directly proportional to the equipment prices, largely determined by the voluntarily submitted invoices for particular equipment items. Therefore, we believe that absent an auditable, robust data source, using anecdotal data for

maintenance costs is likely to compound the current problems of pricing equipment costs accurately, not increase accuracy.

We will continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

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.) We did not propose any changes to these interest rates for CY 2016.

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 Nonfacilit y	33533 CABG, arterial, single Facility	71020 Chest x- ray Nonfacility	71020-TC Chest x- ray, Nonfacilit y	71020-26 Chest x- ray, Nonfacilit y	93000 ECG, complete, Nonfacilit y	93005 ECG, tracing Nonfacilit y	93010 ECG, report Nonfacilit y
(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*		0.5957	0.5957	0.5957	0.5957	0.5957	0.5957	0.5957	0.5957
(6) Adjusted Labor	Steps 2-4		=(1)*(5)	7.93	46.18	3.42	3.42	0	3.04	3.04	0
(7) Adjusted Supplies	Steps 2-4	=Eqp * Dir Adj	=(2)*(5)	1.78	4.37	0.32	0.32	0	0.71	0.71	0
(8) Adjusted Equipment	Steps 2-4	=Sup * Dir Adj	=(3)*(5)	0.1	0.35	4.22	4.22	0	0.05	0.05	0
(9) Adjusted Direct	Steps 2-4		=(6)+(7)+(8)	9.82	50.9	7.96	7.96	0	3.8	3.8	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	1.29	0.1	0.1	0	0.08	0.08	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)	0.27	1.42	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	6.7	0.54	0.54	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd pt)	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)

	Step	Source	Formula	99213 Office visit, est Nonfacilit y	33533 CABG, arterial, single Facility	71020 Chest x- ray Nonfacility	71020-TC Chest x- ray, Nonfacilit y	71020-26 Chest x- ray, Nonfacilit y	93000 ECG, complete, Nonfacilit y	93005 ECG, tracing Nonfacilit y	93010 ECG, report Nonfacilit y
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.32	0.1	0.22	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.8	40.45	0.85	0.63	0.22	0.52	0.35	0.17
(23) Indirect Adjustment (Ind Adj)	Steps 9-11	See Footnote**		0.3816	0.3816	0.3816	0.3816	0.3816	0.3816	0.3816	0.3816
(24) Adjusted Indirect Allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.69	15.44	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	11.71	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	13.16	0.54	0.46	0.08	0.28	0.23	0.06

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 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

This section focusses on specific PE inputs that we addressed in the proposed rule. The direct PE inputs are included in the CY 2016 direct PE input database, which is available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

(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 proposed 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 website reflect the updated price.

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

As we stated in the CY 2015 final rule with comment period (79 FR 67563), we generally believe that workstations used by these practitioners are more accurately considered indirect costs associated with the PC of the service. However, we understand that the professional workstations for interpretation of digital images are similar in principle to some of the previous film inputs incorporated into the global and technical components of the codes. 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 solicited comments on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes.

Comment: Many commenters supported the equipment price increase to \$5,557 for the PACS workstation. Commenters stated that this is a more accurate amount than the current price of \$2,501. However, many commenters, including the RUC, stated that this price did not capture

the appropriate pricing for the PC of the PACS workstation. One commenter expressed concerns with the method that CMS employed to establish the proposed price for the PACS workstation, disregarded the invoices and accompanying explanations submitted by several stakeholders and instead relying on the information submitted by a single group.

Response: We acknowledge and appreciate that several stakeholders provided information intended to facilitate our pricing of the equipment related to PACS. However, much of that submitted information included costs that are considered indirect PE under the established methodology. We considered all of the submitted information and used the submitted prices that were consistent with the principles established under the PE methodology.

Comment: Many commenters, including the RUC, stated that the proposed price did not capture the appropriate pricing for the PC of the PACS workstation. Several commenters indicated that the professional workstation was a direct PE item due to the fact that it is used for individual studies (one at a time) in the non-facility setting, and its use involves a bi-directional exchange between a technologist and a radiologist while the TC is being provided. These commenters also suggested that the professional PACS workstation was a direct proxy for the film alternators, film processors, and view-boxes previously considered direct PE inputs for many of these services prior to the film to digital conversion. Several commenters suggested that the true cost of the PACS workstation was significantly higher than the proposed \$5,557 due to these professional expenses.

Response: We appreciate the extensive feedback regarding the potential addition of a PC to the PACS workstation. We agree that the costs of the professional workstation may be analogous to costs previously incorporated as direct PE inputs for these services. Therefore, we are seeking comments and recommendations from stakeholders, including the RUC, regarding which codes would require the professional PACS workstation and for how many minutes the professional equipment workstation would be used relative to the work time or clinical labor

tasks associated with individual codes. We would address any such recommendations in future rulemaking.

Comment: One commenter stated that the CMS' attempt to analogize elements of a PACS workstation to the historic inputs associated with film technology was inherently flawed. This commenter stated that CMS should not characterize critical elements of the PACS workstation as indirect costs because film technology is fundamentally distinct from digital technology. The commenter indicated that the PACS workstation requires specific software to function, and the costs associated with training, maintenance, and warranties for the PACS workstation have not been factored into the cost of the equipment. The commenter suggested that not including these as direct costs reflects a mistaken assumption that a PACS workstation has functionality for non-imaging services, such as patient scheduling, billing, or electronic medical records capability.

Response: We believe that maintaining consistent treatment of PE costs is of central importance in the resource-based relative value system. Since the PE RVUs for individual services are relative to all other PFS services, we believe that we must categorize typical costs for individual services into the direct and indirect categories using the same definitions that apply to all PFS services. We believe it would be inconsistent with cost-based relative value principles to change the definition of those categories for particular procedures or tests, even when technology changes. Centralized record keeping systems, containing clinical or billing information are considered indirect expenses across the PFS. Due to technological changes, some of these systems are well-integrated into equipment items with clinical functionality, while others remain completely distinct. In pricing and categorizing these costs, we have aimed to separate these costs where possible and believe we have maintained relativity among PFS services to the greatest extent possible. We remind commenters that indirect PE RVUs are included for every nationally priced PFS service and that these RVUs contribute to payment for

each and every service. We also note that over time, indirect costs change as direct costs change. For example, changes in technology might result in particular items using more or less office space, or using more or less electricity. We do not believe it would be appropriate to redefine indirect costs as direct costs whenever we have reason to believe that indirect costs have changed due to changes in technology. Instead, we acknowledge that indirect costs change over time for all those who are paid through the Medicare PFS, making it even more important to follow the established principles of relativity in establishing direct PE inputs.

After consideration of comments received, we are finalizing our proposal to update the price for the PACS workstation to \$5,557 from the current price of \$2,501.

As we noted in the proposed rule, one commenter 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. Therefore, we sought comment from stakeholders, including the RUC, about whether or not the PACS workstation used in imaging codes is the same workstation that is used in the post-processing described by CPT code 76377, or if a more specific workstation should be incorporated in the direct PE input database.

Comment: Multiple commenters indicated that CPT code 76377 requires image post-processing on an independent workstation. Commenters stated that the “computer workstation, 3D reconstruction CT-MR” equipment (ED014), which was removed by the RUC from the equipment list for this procedure, is separate from the PACS workstation and performs a different function. The commenters requested that ED014 be restored to the equipment inputs for CPT code 76377 and assigned 38 minutes of equipment time. The commenters also

suggested that the PACS workstation should remain as a separate direct PE expense as well, since there are additional PACS related activities specific to the 3-D images after they have been created on the computer workstation.

Response: We appreciate the additional information regarding the use of the 3D reconstruction computer workstation for CPT code 76377. After consideration of comments received, we agree that the “computer workstation, 3D reconstruction CT-MR” equipment (ED014) should be restored to the equipment list and assigned to CPT code 76377 with an equipment time of 38 minutes. However, we do not believe that the typical service for CPT code 76377 would also use the PACS workstation. Therefore, we substituted ED014 in place of the PACS workstation.

(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.

Although 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 solicited comments 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 final 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 protocolled 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.

The following is a summary of the comments we received regarding whether these standard times accurately reflect the typical time it takes to perform these clinical labor tasks associated with digital imaging.

Comment: Many commenters supported CMS’ efforts to recognize the advances in digital technology and take them into account through updated RVUs. Several commenters agreed that the clinical labor tasks outlined in Table 5 reflected the PE Subcommittee’s film to digital workgroup recommendations. The commenters suggested that the staff types in the tasks should be made more generalized and less specific (such as technologist to clinical staff or radiologist to physician), and stated that specialty societies should be afforded the opportunity to request deviations (that is, increases) from the standard times.

Response: We believe that providing specific guidelines for the staff types associated with these tasks will aid in determining the most accurate value for each service. We also agree

that specialties should be afforded the opportunity to request deviations from the standard times for unusual situations, when supported with the presentation of additional justification for the added time.

Comment: The RUC commented that it had not supported standard times for clinical staff activities related to digital imaging in the past, as the RUC had recommended that the specialties should have an opportunity to determine the appropriate inputs at the individual distinct service level and there was too much variability across imaging modalities to propose standards. While the RUC continued to hold to its previous position on this subject, it also agreed that four of the five clinical labor activities proposed by CMS in Table 5 are representative across imaging and could appropriately be used as standard times. The one exception was the clinical labor task “Technologist QC’s images in PACS, checking for all images, reformats, and dose page”, in which the RUC stated the number of minutes would vary significantly depending on the procedure in question. For example, a cardiac MR with hundreds of images would require more quality control time than a single view X-ray of the chest. The RUC recommended that this line item remain nonstandard, and that specialties should continue to have the opportunity to make a recommendation on the appropriate number of minutes based on clinical judgment.

Another commenter also supported standard clinical labor times for four out of the five tasks associated with digital technology, again excepting the activity “Technologist QC’s images in PACS, checking for all images, reformats, and dose page.” This commenter stated that a survey of imaging providers had been conducted which suggested that the median time required to perform this clinical labor task was 10 minutes. The commenter stated that CMS did not have any data to support its belief in the standard time of 2 minutes, and recommended considering the commenter’s data and information from other stakeholders regarding the appropriate standard minutes for the clinical labor tasks associated digital imaging.

Response: With regard to the activity “Technologist QC’s images in PACS, checking for all images, reformats, and dose page”, we agree that this task may require a variable length of time depending on the number of images to be reviewed. We believe that it may be appropriate to establish several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in the same fashion that the clinical labor assigned to clean a surgical instrument package has two different standard times depending on the use of a basic pack (10 minutes) or a medium pack (30 minutes). We are interested in soliciting public comment and feedback on this subject, with the anticipation of including a proposal in next year’s proposed rule.

After consideration of comments received, we are finalizing standard times for clinical labor tasks associated with digital imaging at 2 minutes for “Availability of prior images confirmed”, 2 minutes for “Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist”, 2 minutes for “Review examination with interpreting MD”, and 1 minute for “Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.” We are not finalizing a standard time for clinical labor task “Technologist QC’s images in PACS, checking for all images, reformats, and dose page” at this time, pending consideration of any additional public comment and future rulemaking, as described above.

(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 supports the judgment that the same tasks take significantly more or less time depending on

the individual service for which they are performed, especially given the specificity with which they are described.

Therefore, we developed standard times that we have used in finalizing 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 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 solicited comments 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 (minutes)
Accession specimen/prepare for examination	4
Assemble and deliver slides with paperwork to pathologists	0.5
Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation	0.5
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

Clinical Labor Task	Standard Clinical Labor Time (minutes)
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

Comment: Many commenters stated that they did not support the standardization of clinical labor activities across pathology services. Commenters stated that a single standard time for each clinical labor task was infeasible due to the differences in batch size or number of blocks across different pathology procedures. Several commenters indicated that it may be possible to standardize across codes with the same batch sizes, and urged CMS to consider pathology-specific details, such as batch size and block number, in the creation of any future standard times for clinical labor tasks. One commenter stated that the CMS clinical labor times were uniformly too low, and that CMS did not provide enough information about how it arrived at these revised standard times. The commenter provided five examples of inadequate labor times, and stated that CMS should provide stakeholders with information about the source of its data and why it rejected the RUC recommendations for these clinical labor tasks.

Response: We appreciate the extensive feedback provided by commenters on the standard times for clinical labor tasks associated with pathology services. As we stated in the CY 2016 PFS proposed rule, we developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that clinical labor tasks with the same work description are comparable across different pathology procedures. We concur with commenters that accurate clinical labor

times for pathology codes may be dependent on the number of blocks or batch size typically used for each individual service. However, we believe that it is possible to establish “per block” standards or standards varied by batch size assumptions for many clinical labor activities that will be comparable across a wide range of individual services. We have received detailed information regarding batch size and number of blocks during review of individual pathology services on an intermittent basis in the past. We request regular submission of these details on the PE worksheets as part of the review process for pathology procedures, as a means to assist in the determination of the most accurate direct PE inputs. Were we to receive this information as part of standard recommendations, we would include these assumptions as part of the information open for comment in proposed revaluations. We are also seeking comment regarding how to best establish clinical labor standards for pathology services on a “per block” or “per batch size” basis.

We also believe that many of the clinical labor activities that we discussed in Table 6 are tasks that do not depend on number of blocks or batch size. Clinical labor activities such as “Clean room/equipment following procedure” and “Dispose of remaining specimens” would typically remain standard across different services without varying by block number or batch size, with the understanding of occasional allowance for additional time for clinical labor tasks of unusual difficulty.

After consideration of comments received, we are finalizing standard times for clinical labor tasks associated with pathology services at 4 minutes for “Accession specimen/prepare for examination”, 0.5 minutes for “Assemble and deliver slides with paperwork to pathologists”, 0.5 minutes for “Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation”, 1 minute for “Clean room/equipment following procedure”, 1 minute for “Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste”, and 1 minute for “Prepare, pack and

transport specimens and records for in-house storage and external storage (where applicable).”

We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks. For the rest of the clinical labor tasks associated with pathology services, we are interested in soliciting further public comment and feedback on this subject as part of this final rule with comment period, with the anticipation of including a proposal in next year’s proposed rule.

(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 proposed 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 website were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

The following is a summary of the comments we received regarding the clinical labor task “complete botox log.”

Comment: Several commenters, including the RUC, did not agree with the proposal to eliminate the minutes associated with this clinical labor task. Commenters maintained that the clinical labor task of completing the botox log was a medically reasonable direct resource cost. One commenter stated that it was critical for clinical staff to maintain accurate bookkeeping of split botox vials, and that documentation must reflect the exact dosage of the drug given to patients and a statement that the unused portion of the drug was discarded.

Response: We continue to believe that the clinical labor assigned for the task “complete botox log” is a form of indirect PE that is not allocated to individual services. We believe that

this is a quality control issue for clinical staff. Maintaining accurate administrative records, even for public safety, is not a task we generally allocate to individual services, instead we consider these costs as attributable across a range of services, and therefore, as an indirect PE. After consideration of comments received, we are finalizing the proposal to eliminate the minutes assigned for the task “complete botox log” from the 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 proposed 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 website 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 proposed 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”) we proposed 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 proposed 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 website were calculated with the inputs displayed in the CY 2016 direct PE input database.

The following is a summary of the comments we received regarding clinical labor input inconsistencies.

Comment: Two commenters indicated that although they appreciated CMS’ efforts to clean up errors in the direct PE database, they had specific concerns regarding the proposed changes. The commenters stated that for CPT code 22510, it appeared that the direct PE clinical time file had the second technologist listed at 90 minutes for the “Assist physician” task, not 45 minutes as recommended. The commenters indicated that CMS stated an intention to include 5 minutes for “Check dressings & wound” but this time did not appear to be included in the direct PE input labor file. The commenters also noted that the postoperative E/M visit for CPT code 22510 was also not listed in the CMS file.

The commenters stated that for CPT code 22511, the CMS direct PE labor file correctly included the 45 minutes of “Assist physician” time for the second technologist, however, the 5 minutes for the RN/LPN/MTA blend (L037D) to “Check dressings & wound” was still not included in the CMS file. The commenter indicated that the postoperative E/M visit was also not included for this code. The commenters also stated that for CPT code 22514, CMS was proposing to include the 5 minutes for “Check dressings & wound” in the intraservice time for this service. The commenters indicated that this did not appear to be consistent with how CMS

was proposing to handle the same clinical labor task in the prior two codes discussed. The commenters requested that CMS outline specifically which line items (from the PE spreadsheet) it proposed to change and the effects these changes would have on the direct inputs for these three codes.

Response: We appreciate the detailed feedback from the commenters on the clinical labor inconsistencies in these three codes. We agree with the commenters that there were remaining clinical labor errors in these procedures beyond those detailed in the CY 2016 PFS proposed rule, and appreciate the opportunity to clarify the discrepancies in clinical labor for these three procedures.

For CPT code 22510, we agree with the commenters that the clinical labor assigned to the RadTech (L041B) for “Assist Physician” was incorrectly listed twice in our direct PE input database. The clinical labor staff type was also incorrectly entered as L041C, which is priced at the same rate but refers to a second Radiologic Technologist for Vertebroplasty. We will remove the duplicative clinical labor and assign type L041B to the “Assist Physician” activity. We do not agree with the commenters that the time for clinical labor task “Check dressings & wound” was missing, as it is present in the database. We agree with the commenters that the clinical labor time for the office visit was missing from CPT code 22510, and we will add it to the direct PE database.

For CPT code 22511, the commenters are correct that the time for clinical labor task “Assist physician” was entered at the correct value of 45 minutes, and the 5 minutes of clinical labor for “Check dressings & wound” does not appear in the non-facility setting. This clinical labor time appears to have been incorrectly entered for the facility setting instead; we will remove this time and add it to its proper non-facility setting. We agree with the commenters that the clinical labor time for the office visit was again missing from CPT code 22511, and we will add it to the direct PE input database.

For CPT code 22514, the time for clinical labor task “Assist physician” has been refined to 50 minutes as detailed in the CY 2016 PFS proposed rule. We agree with the commenters that the 5 minutes of clinical labor time for “Check dressings & wound” is missing from the direct PE input database. We agree that the clinical labor for this activity should not be treated differently from the rest of the codes in the family, and therefore these 5 minutes are included in the direct PE input database. The postoperative office visit is included in the direct PE input database for CPT code 22514.

After consideration of comments received, we are finalizing our proposed changes to clinical labor along with the additional corrections described above.

(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 proposed 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 website were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

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

(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 proposed 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.

Comment: Several commenters strongly supported the CMS proposal to create a new supply code for Spherusol that reflects the current price for the antigen and to update the direct inputs for CPT code 86490 to include this item. However, commenters noted that the public use files included in the CY 2016 PFS proposed rule continue to reflect the prior supply code SH006 with a price of \$4.10. Commenters asked whether this was a technical error and urged CMS to correct the input files to be consistent with the proposal described in the regulation preamble.

Response: We appreciate support for our proposal and acknowledge our inadvertent omission of this change in the proposed direct PE input database. After consideration of comments received, we are finalizing our proposal to create a supply item for Spherusol and it is included as a direct PE input for CPT code 86490.

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.

In the proposed rule, we stated that we 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 proposed to change the price for EQ340 (Patient Worn Telemetry System) to \$23,537. The PE RVUs displayed in Addendum B on the CMS website were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

Comment: One commenter supported the CMS proposal regarding the Patient Worn Telemetry System (EQ340). The commenter agreed with the proposed increase in the price of the equipment from \$21,757 to \$23,537, and the reason for this increase. We did not receive any comments opposing the proposal.

Response: After consideration of comments received, we are finalizing our proposal regarding the Patient Worn Telemetry System equipment.

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, in the CY 2015 proposed rule, 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 solicited comments 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 solicited 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.

Comment: Several commenters disagreed with the CMS proposal regarding the updated price for the supply item “kit, HER-2/neu DNA Probe” (SL196). One commenter stated that the price of \$94 reflected a volume discount that could not be obtained by the typical provider. The lowered price referenced in the CY 2016 PFS proposed rule indicated that the purchaser may be receiving a competitive contractually arranged price. The commenter stated that the lowered price referenced is what might be expected to be acquired by the largest hospitals, which would be expected to buy supplies in greater volume than a small community hospital or mid-sized laboratory, and the price indicated does not reflect the prices for a laboratory of typical size. Other commenters stated that they were unable to find this pricing information through publicly available sources, suggesting that it may not reflect typical transactions. The commenters also stated that it was unclear as to whether the proposed price referred to FDA-approved kits, which are more expensive than non-approved kits. The commenters further indicated that a number of new morphometric analysis, multiplex quantitative/semi-quantitative ISH tests are in use today

with probe kit costs that are higher than those of HER-2/neu probe kits. The commenters suggested that CMS should adopt a weighted-average of the probe kit prices for the probe kits currently used to perform these procedures.

Response: Without robust, auditable information regarding the actual prices paid by a range of practitioners that would allow us to reasonably determine a recommended price to be typical, we believe that we should assume that the best publicly available price is typical. Generally speaking, we do not believe vendors are likely to allow public display of pricing that is not broadly available to potential customers since that would present significant competitive disadvantages in the market. Therefore, given the options between the best publicly available price or prices on invoices selected for the distinct purpose of pricing individual services, we believe the best publicly available price is more likely to be typical. Therefore, we are not making any changes to the price of this supply item at this time.

Comment: The RUC commented that in the CMS direct PE database the unit of measure for SL196 is listed as “kit”, while on the submitted PE spreadsheet the unit is listed as “kit assay.” The RUC recommended that the unit of measure be changed to “kit assay” to correlate correctly with the cost shown in the database.

Response: We appreciate this additional information, and will change the unit of measure of SL196 to “kit assay” in the direct PE database.

Comment: Several commenters stated CMS’s estimated per-minute labor cost inputs are too low for laboratory technicians (L033A), cytotechnologists (L045A) and histotechnologists (L037B). The commenters stated that the complexity of many laboratory services demands highly-skilled, highly-trained, certified, and experienced personnel who typically must be paid higher wages than the current rates provided by CMS. Commenters stated that CMS has underestimated the actual labor costs associated with the work that these more specialized

laboratory personnel perform by 20 to 30 percent, after accounting for costs related to benefits, taxes, and training.

Response: The clinical labor costs per minute are based on data from the Bureau of Labor Statistics. We believe that it is important to update that information uniformly among clinical labor types and will consider updating the clinical labor costs per minute in the direct PE database in future rulemaking.

(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.H. 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.

Comment: Several commenters addressed the number of blocks and batch size for prostate biopsies in particular. We direct readers to section II.H. of this final rule with comment period for a more detailed discussion of the resource costs for these services. We continue to

seek stakeholder input regarding the best sources of information for typical number of blocks and batch sizes for pathology services.

d. Developing Nonfacility Rates

We noted 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 noted 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). We have 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. As discussed in the proposed rule, we believe that it now may be 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 also noted in the proposed rule that we believe 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 solicited comments from ophthalmologists and other stakeholders on office-based surgical suite cataract surgery. In addition, we solicited comments from the RUC and other stakeholders on the direct PE inputs involved in furnishing cataract surgery in the nonfacility setting in conjunction with our consideration of information regarding the possibility of development of nonfacility cataract surgery PE RVUs.

We received 138 comments from stakeholders including professional medical societies, the RUC, ambulatory surgical centers (ASCs), practitioners, and the general public. The RUC deferred to the specialty societies regarding the appropriateness of performing these services in the nonfacility setting.

Comment: A few commenters suggested that development of PE RVUs would allow for greater flexibility regarding scheduling and location where services are performed. Commenters provided information about clinical considerations related to furnishing these services in a nonfacility setting, with many commenters citing safety concerns involved in furnishing cataract surgery in the office setting.

Response: We will use this information as we consider whether to proceed with development of nonfacility PE RVUs for cataract surgery.

(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 solicited input from stakeholders, including the RUC, about the appropriate direct PE inputs for these services.

We received 53 comments from stakeholders including specialty societies, device manufacturers, medical centers, and physician practices (otolaryngology, allergy, facial, and plastics specialists).

Comment: The RUC indicated an intention to review direct PE inputs at the January 2016 RUC meeting. One specialty society representing otolaryngology head and neck surgeons indicated that endoscopic sinus surgery services have been identified by the CPT/RUC workgroup for development of bundled codes for this code family and inputs will likely be reviewed as part of this process. Some commenters submitted information about their respective PEs related to CPT codes 31254, 31255, 31267, 31276, 31287, and 31288. Other commenters limited their comments to CPT codes 31254 and 31255, noting clinical concerns about

performance of other sinus surgery procedures in the nonfacility setting. A few commenters did not support development of nonfacility direct PE RVUs for endoscopic sinus surgery due to clinical considerations such as patient safety, possible complications, use of anesthesia, and need for establishment of standards and oversight of in-office surgical suites.

Response: We appreciate the feedback we received from all commenters. We will use this information as we consider whether to proceed with development of nonfacility PE RVUs or functional endoscopic sinus surgery 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 composed of three components: work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based.

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 were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or “scale”) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the 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 proposed to continue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we proposed work RVUs and

PE inputs, we also published the proposed MP crosswalks used to determine their MP RVUs. The MP crosswalks for those new and revised codes were subject to public comment and we are responding to comments and finalizing them in section II.H. of this CY 2016 PFS final rule with comment period. The MP crosswalks for new and revised codes with interim final values established in this CY 2016 final rule with comment period will be implemented for CY 2016 and subject to public comment. We will then respond to comments and finalize them 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 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 proposed 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 5 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 also proposed 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 proposed 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 that we are finalizing for 2016.) To determine the specialty mix assigned to each code, we also proposed to use the same process used in the PE methodology, described in section II.2.b.(6) of this final rule with comment period. We note that for CY 2016, we proposed and are finalizing a policy 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. 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 also proposed 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 did not propose 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 serve to balance the advantages of using annually updated information with the need for year-to-year stability in values. We solicited comments 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 solicited comments 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.

The following is a summary of the comments we received regarding our current approach for determining malpractice RVUs for new/revised codes.

Comment: Several commenters, including the RUC, generally supported CMS' proposal to update the MP RVUs on an annual basis. Commenters, including the RUC, stated a preference for the annual collection of professional liability insurance (PLI) premium data to insure the MP RVUs for every service is accurate, as opposed to only collecting these data every five years.

Response: We appreciate commenters' support of our proposal to update the MP RVUs on an annual basis. We also appreciate the comments from stakeholders regarding the frequency that we currently collect premium data. We will continue to consider the appropriate frequency for doing so, and we would address any potential changes in future rulemaking.

Comment: Commenters, including the RUC, support CMS's proposal to use the 3 most recent years of available data for the specialty mix assignment.

Response: We appreciate the commenters' support.

Comment: Commenters supported CMS' proposal to maintain the code-specific overrides established in previous rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service. Commenters also requested that CMS publish the list of overrides annually to receive stakeholder feedback related to necessary modification to the list, and in an effort to be as transparent as possible.

Response: We appreciate the comments and agree that we should increase the

transparency regarding the list of services with MP RVU overrides. Publication of this list will also allow commenters to alert us to any discrepancies between MP RVUs developed annually under the new methodology and previously established overrides. Therefore, we have posted a public use file containing the overrides. The file is available on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

Comment: One commenter stated that CMS should be particularly mindful of using the specialty mix in the Medicare claims data for services with low Medicare volume but high volume in the United States health care system more generally, such as pediatric procedures; and that CMS' MP RVU methodology needs to differentiate between services that are truly low volume and those that occur frequently, but not among Medicare beneficiaries.

Response: We believe that the list of overrides we are making available as a public use file on the CMS website will help address the commenter's concern since the purpose of the code-specific overrides is to address circumstances where the claims data are inconsistent with the specialty that could be reasonably expected to furnish the service. We have previously accepted comment on services like those identified by the commenter and will continue to consider comments regarding the need to use overrides for particular services, especially for high volume services outside the Medicare population.

Comment: One commenter requested that CMS continue to use the dominant specialty for low volume codes.

Response: We acknowledge the concern about using the dominant specialty for low volume codes, and will continue to monitor the resulting RVUs to determine if adjustments become necessary. In general, we believe the 3-year average mitigates the need to apply the dominant specialty for low volume services. However, we have a long history of applying the dominant specialty for low volume services in instances where the specialty indicated by the

claims data is inconsistent with the specialty that could be reasonably expected to furnish the service, and we are maintaining that practice.

Comment: Some commenters requested more information on how specialty impacts were determined. Two commenters expressed concerns about the estimated impact of the several proposed changes in the MP methodology on some specialties—particularly gastroenterology, colon and rectal surgery, and neurosurgery. Those commenters state that they appreciate the assertion that it may be difficult to obtain premium data for some specialties, such as neurosurgery, and state that CMS must thoroughly vet the methodology used by its contractor to determine MP premiums for such specialties. The commenters urge CMS to review the data, continue to try to obtain premium data in as many states as possible, and to share the data with the public for the agency and specialties to determine its accuracy.

Response: Specialty impacts are determined by comparing the estimated overall payment for each specialty that would result from the proposed RVUs and policies to the estimated overall payment for each specialty under the current year RVUs and policies, using the most recent year of available claims data as a constant. We note that for MP RVUs, there were several refinements that resulted in minor impacts to particular specialties, especially those at the higher end of specialty risk factors. We believe that these impacts are consistent with the general tendency of greater change in MP RVUs for specialties with risk factors of greater magnitude. We agree with the commenters regarding the importance of making certain that the collection of premium data and the methodology of calculating MP RVUs are as accurate as possible. This is the reason we continue to examine the methodology and develop technical improvements such as the ones described in this section of the final rule. Additionally, we believe that annual calibration of MP RVUs will be likely to reduce the risk of irregularities, since we will regularly compare MP RVUs for individual codes and for specialties between consecutive years instead of only comparing MP RVUs update years.

After consideration of the public comments received, we are finalizing the policies as proposed. That is, we are finalizing the proposal to conduct annual MP RVU updates to reflect changes in the mix of practitioners providing services and to adjust MP RVUs for risk, and 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. We note that we will continue to maintain the code-specific overrides where the claims data are inconsistent with a specialty that would reasonable be expected to furnish the services.

We also proposed 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 proposed 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 only proposed to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005.

Comment: Several commenters, including the RUC, opposed CMS' proposal to remove the MP RVU floor of 0.01 for add-on services. These commenters suggested that the

incremental risk associated with performing an additional procedure is not mitigated by the risk inherent in the base procedure. Another commenter stated that each service should be considered separately for the purposes of calculating MP RVUs, and therefore, each service should be given the 0.01 floor regardless of base or add-on status.

Response: We appreciate commenters' feedback, but note that we do not believe the comments respond to the rationale for the proposed refinement. We agree that the incremental risk in procedures described by add-on codes is not mitigated by the risk inherent in the base procedure. That is why we did not propose to eliminate MP RVUs for add-on codes generally. Instead, we believe that when the incremental risk is calculated to be a number closer to 0.00 than 0.01, we do not believe that rounding such a number to 0.01 accurately reflects the risk of the service that is described by two codes (base code and add-on) relative to the risks associated with other PFS services. We continue to believe that this refinement is the most appropriate approach, since we would continue to account for the incremental risk associated with add-on codes without overestimating the risk in circumstances where the MP RVU falls below 0.005. Therefore, we are finalizing the policy as proposed.

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, to appropriately update the MP resource costs for anesthesia, we proposed to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the 5 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 final rule with comment period for the Anesthesia Fee Schedule Conversion Factors for CY 2016. We invited public comments regarding this proposal.

The following is a summary of the comments we received regarding this proposal.

Comment: We received few comments with regard to our proposal; commenters expressed appreciation that CMS recognized the unique aspects involved in updating the MP component associated with anesthesia services, and therefore, delayed the anesthesia MP update until the CY 2016 PFS.

Response: We appreciate the commenters' feedback, and we are finalizing the policy as proposed.

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 website. 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 the CY 2016 PFS proposed rule, we identified a necessary refinement to way we 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 proposed 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 proposed 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 final MP RVUs, as displayed in Addendum B of this final rule with comment period, reflect MP RVUs calculated following our established methodology, with the inclusion of the proposals and refinements described above.

Comment: Commenters generally supported the technical changes to the MP RVU methodology and found them reasonable. One commenter stated that such refinements will increase stability of MP RVUs and does a better role of capturing the role of each local area's premium in the "national" premium for each specialty.

Response: We appreciate the commenters' support, and we are finalizing the policy as proposed.

Comment: One commenter stated that the MP RVU for cataract and other ophthalmic surgeries is deflated significantly because CMS assumes that optometry is providing the actual surgical portion of the procedure, when there is no state that allows optometrists to perform cataract surgery or any other major ophthalmic procedure. The commenter states that the clinical reality is that optometry is involved only during the pre- or post- procedure time period, and CMS should not allow optometric utilization of those codes with co-management modifiers to be included in the calculations for any major ophthalmic surgical procedures. The commenter suggested that if CMS does not agree to remove optometry from the calculation of MP RVUs for ophthalmic surgery, that CMS should use a much lower percentage of utilization to accurately reflect the true risk that optometrists encounter during this limited portion of the service. The commenter also disagreed that all providers who pay for malpractice insurance should have their premiums taken into consideration, and stated that when CMS looks at the dominant specialty for a given service, it must ensure that the claims reported—particularly by non-physician

providers such as optometrists, are for the surgical portion of the procedure for which the MP RVU is being considered.

Response: We would clarify for the commenter that we apply the risk factor(s) of all specialties involved with furnishing services to calculate the service level risk factors for all PFS codes. Our methodology already accounts for codes with longer global periods or codes where two different practitioners report different parts of the service, weighing the volume differentially among the kinds of practitioners that report the service depending on which portion of the service each reports. We also remind commenters that, to determine the raw MP RVU for a given service, we consider the greater of the work RVU or clinical labor RVU for the service. Since the time and intensity of the pre-service and post-service period are incorporated into the work RVUs for these services and the work RVUs are used in the development of MP RVUs, we believe it is methodologically consistent to incorporate the portion of the overall services that is furnished by practitioners other than those that furnish the procedure itself in the calculation of MP RVUs. If we were to exclude the risk factors of some specialties that bill a specific code from the calculation of the service level risk factor, the resulting MP RVU would not reflect all utilization. Likewise, we also disagree with the suggestion that the pre- and post- utilization should be removed from determining MP RVUs for ophthalmic surgical services. The resources associated with pre- and post-operative periods for ophthalmic surgery are included in the total RVUs for the global surgical package. Accordingly, if we did not include the portion of utilization attributed to pre- and post-operative visits in the calculation of service level risk factors, the MP RVUs for global surgery would overstate the relative MP costs.

Comment: One commenter identified three low volume codes typically performed by cardiac surgery or thoracic surgery that have anomalous MP RVU values: CPT code 31766 (carinal reconstruction), the commenter requested that the MP risk factor associated with Thoracic surgery be assigned; CPT Code 33420 (valvotomy, mitral valve; closed heart), the

commenter requests that the MP risk factor associated with Cardiac Surgery be assigned; and for 32654 (thorascoscopy, surgical; with control of traumatic hemorrhage), the commenter requests that the MP risk factor associated with Thoracic surgery be assigned.

Response: We agree with the commenters and have added these services to the list of those with specialty overrides for CY 2016. We hope to identify such anomalies more regularly in the future now that the public use file listing the overrides is available on the CMS website as indicated above.

5. 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). Members of the public including direct 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 is not limited to, the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in 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 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 periods for 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 that the labor costs for nursing staff were 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. Based on the requestor's comment, we proposed this code as a potentially misvalued code. We also noted 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).

Comment: Several commenters stated that they do not believe CPT code 36516 is potentially misvalued because they found no indication that the clinical staff time, indirect expenses, or work was misvalued. All commenters requested that this code be removed from the potentially misvalued list.

Response: We appreciate the comments, but we believe that the nominator presented some concerns that may have merit, and review of the code is the best way to determine the validity of the concerns articulated by the original requestor. Therefore, we are adding CPT code 36516 to the list of potentially misvalued codes and anticipate reviewing recommendations from the RUC and other stakeholders.

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 PE inputs were inaccurate, including the cost of the implant. We proposed these services as potentially misvalued codes.

Comment: Some commenters disagreed that the commenter intended to nominate CPT codes 52441 and 52442 as potentially misvalued.

Response: After reviewing the original comment, we agree with these commenters' perspective that the intention was not to nominate the codes as potentially misvalued. Therefore, we are not finalizing our proposal to review these codes under the potentially misvalued code initiative.

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

In the CY 2015 final rule with comment period (79 FR 67670), we reviewed and valued all of the inputs for the following 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)). Due to significant time changes in the base codes, we believe the entire family detailed in Table 7 is potentially misvalued and should be reviewed in a manner consistent with our review of CPT codes 95971, 95972 and 95973.

TABLE 7: 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.

Comment: One commenter agreed with the review of CPT codes 95970-95982 as potentially misvalued services.

Response: We are adding CPT codes 95970-95982 to the list of potentially misvalued codes and anticipate reviewing recommendations from the AMA RUC and other stakeholders.

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).

As detailed in the CY 2016 PFS proposed rule (80 FR 41706), we believed that our current resources will not necessitate further delay in proceeding with the high expenditure screen for CY 2016. Therefore, we re-ran the screen with the same criteria finalized in last year’s final rule. However, in developing this CY 2016 proposed list, we also 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 described in section II.B.6. of this final rule with comment period.

We proposed 118 codes 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 the list, we followed the same approach taken last year except we excluded codes with 10- and 90- day global periods. Specifically, we identified the top 20 codes by specialty (using the specialties used in Table 64 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 described 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).

Comment: Some commenters did not believe that high expenditure/high volume was an appropriate criterion for us to use to identify the codes for the potentially misvalued codes initiative. These commenters stated that high expenditure is not an objective gauge of potential misvaluation. Additionally, commenters believed that selecting codes that have not been reviewed in the past 5 years insinuates that the delivery of these services and procedures has changed radically over that time span, which many doubted. Other commenters believed CMS should provide justification for the revaluation by providing evidence and/or data to show how the delivery of a service or procedure has changed within 5 years. While many disagreed with our use of the high expenditure screen, some commenters specifically suggested use of different types of screens; some of which would screen for services for which volume has increased a certain percentage over a set period or screen for changes in the predominate site of service.

Response: We appreciate commenters’ perspective on the proposed list of potentially misvalued codes based on the high expenditure screen. It is clear that over time the resources

involved in furnishing particular services can often change and, therefore, many services that have not recently been evaluated may become potentially misvalued. Under section 1848(c)(2)(B) of the Act, we are mandated to review relative values for codes for all physicians' services at least every 5 years. The purpose of specifically identifying potentially misvalued codes through particular screens established through rulemaking is to prioritize the review of individual codes since comprehensive, annual review of all codes for physicians' services is not practical and, due to the need to maintain relativity, changes in values for individual services can have an impact across the PFS. We identify potentially misvalued codes in order to prioritize review of subsets of PFS services. We prioritize review of individual services based on indications that a particular code is likely to be misvalued and on the impact that the potential misvaluation of the code would have on the valuation of PFS services broadly. Our high expenditure screen is largely intended to address the latter situation where improved valuation would have the most significant impact on the valuation of PFS services more broadly. This approach is also consistent with another category of codes identified for screening by statute: codes with high PE relative value units. In proposing to prioritize this list of high expenditure codes, we stated that the reason we identified these codes is because they have significant impact on PFS payment on a specialty level and have not been recently reviewed.

Comment: A few commenters suggested that E/M services should not be exempt from review as potentially misvalued codes.

Response: In the CY 2012 final rule (76 FR 73063), we explained the concerns expressed by commenters that informed our decision to refrain from finalizing our proposal to review 91 E/M codes as potentially misvalued. We believe that those concerns remain valid. We also believe that it is best to exempt E/M codes from our review of potentially misvalued codes since we are continuously exploring valuations of E/M services, potential refinements to the PFS, and other options for policies that may contribute to improved valuation of E/M

services.

Comment: Many commenters also stated that the review of codes over such a short time span puts significant burden on the specialty societies. Many commenters agreed that high expenditure codes should be reviewed on a periodic basis over multiple years. Some commenters specifically suggested that the periodic basis should be 10 years while others suggested delaying any review of the codes until after the misvalued code target has been met.

Response: Because of the concerns expressed by commenters about the burden associated with code reviews, we continue to believe that it is appropriate to prioritize review of codes to a manageable subset that also have a high impact on the PFS and work with the specialty society to spread review of the remaining codes identified as potentially misvalued over a reasonable timeframe. Therefore, we do not believe it would be appropriate to remove codes from the high expenditure list unless we find that we have reviewed both the work RVUs and direct PE inputs for the code during the specified time period.

Also, we believe that the resources involved in furnishing a service can evolve over time, including the time and technology used to furnish the service, and such efficiencies could easily develop in a time span as short as 5 years. As a result, we continue to believe that the review of these high expenditure codes is necessary to ensure that the services are appropriately valued. Additionally, not only do we believe that regular monitoring of codes with high impact on the PFS will produce a more accurate and equitable payment system, but we have a statutory obligation under section 1848(c)(2)(B) of the Act to review code values at least every 5 years (although we do not always conduct a review that involves the AMA RUC). Therefore, we do not agree with the commenter that suggested that changes in technology and practice can be effectively accounted for through review of code values every 10 years.

Comment: Commenters stated that the following codes were reviewed since CY 2010 and, as a result, do not fit the criteria for the high expenditure screen and should be removed:

CPT codes 51728 (Insertion of electronic device into bladder with voiding pressure studies), 51729 (Insertion of electronic device into bladder with voiding and bladder canal (urethra) pressure studies), 76536 (Ultrasound of head and neck), 78452 (Nuclear medicine study of vessels of heart using drugs or exercise multiple studies), 92557 (Air and bone conduction assessment of hearing loss and speech recognition), 92567 (Eardrum testing using ear probe), 93350 (Ultrasound examination of the heart performed during rest, exercise, and/or drug-induced stress with interpretation and report) and 94010 (Measurement and graphic recording of total and timed exhaled air capacity).

Response: We agree with commenters that the codes identified do not fit the criteria for review based on the high expenditure screen. Therefore, we are not proposing to review CPT codes 51728, 51729, 76536, 78452, 92557, 92567, 93350, and 94010 under the potentially misvalued code initiative.

Comment: Commenters believed that services that are add-ons to the excluded 10- and 90-day global services should be removed from the list of codes identified through the high expenditure screen in order to maintain relativity. The specific codes suggested for removal were: CPT codes 22614 (Fusion of spine bones, posterior or posterolateral approach); 22840 (Insertion of posterior spinal instrumentation at base of neck for stabilization, 1 interspace); 22842 (Insertion of posterior spinal instrumentation for spinal stabilization, 3 to 6 vertebral segments); 22845 (Insertion of anterior spinal instrumentation for spinal stabilization, 2 to 3 vertebral segments); and 33518 (Combined multiple vein and artery heart artery bypasses).

Response: We agree with the commenters that the codes identified should be removed from the list of codes identified for review through the high expenditure screen due to their relationship to the 10- and 90-day global services that were excluded from our screen. Although we agree that these codes should be removed from this screen, we think it is worthwhile to note that for similar reasons, we believe we should consider these and similar add-on codes in

conjunction with efforts to improve the valuation and the global surgery packages as described in section II.B.6. of this final rule with comment period. Therefore, we are not including CPT codes 22614, 22840, 22842, 22845 on the list of codes identified for review through the high expenditure screen.

Comment: Commenters believed that CPT code 92002 (Eye and medical examination for diagnosis and treatment, new patient) is considered an ophthalmological evaluation and management (E/M) service and as a result, should be excluded for all the same reasons we excluded other E/M codes.

Response: We agree with commenters that CPT code 92002 is considered an E/M and, as a result, should be excluded from the screen as were other E/Ms. Therefore, we are not including CPT code 92002 on the list of codes identified for review through the high expenditure screen.

Comment: A few commenters requested that codes with a work RVU equal to 0.00 (CPT codes 51798 (Ultrasound measurement of bladder capacity after voiding), 88185 (Flow cytometry technique for DNA or cell analysis), 93296 (Remote evaluations of single, dual, or multiple lead pacemaker or cardioverter-defibrillator transmissions, technician review, support, and distribution of results up to 90 days), 96567 (Application of light to aid destruction of premalignant and/or malignant skin growths, each session), and 96910 (Skin application of tar and ultraviolet B or petrolatum and ultraviolet B)) or equal to 0.01 (CPT codes 95004 (Injection of allergenic extracts into skin, accessed through the skin)) be removed from the list of codes identified for review through the high expenditure screen. Commenters stated that historically, services with 0.00 work RVUs were excluded from screens and that re-reviewing a service with a 0.01 work RVU would most likely not lower the work component unless work was completely removed from the code.

Response: We continue to believe that codes with 0.00 work RVUs or very low work

RVUs of 0.01, should still be reviewed and can still be considered potentially misvalued. As stated earlier, we do not believe it would be appropriate to remove codes from the high expenditure list unless we find that we have reviewed both the work RVUs and direct PE inputs. Therefore, we are maintaining CPT codes 51798, 88185, 93296, 96567, 96910 and 95004 as potentially misvalued codes and anticipate reviewing recommendations from the AMA RUC and other stakeholders.

Comment: Various commenters objected to the presence of individual codes that met the high expenditure screen criteria based on absence of clinical evidence that the individual services are misvalued.

Response: We reviewed each of these comments, and believe that these kinds of assessments are best addressed through the misvalued code review process. As we describe in this section, the criteria for many misvalued code screens, including this one, are designed to prioritize codes that may be misvalued not to identify codes that are misvalued. Therefore, we believe that supporting evidence for the accuracy of current values for particular codes is best considered as part of the review of individual codes through the misvalued code process.

Comment: Several commenters believed that codes that are currently scheduled to be considered by either the CPT Editorial Panel for new coding or the RUC for revised valuations (for work RVUs and/or PE inputs) at an upcoming meeting should be removed from the screen. Commenters also believed that it was best to allow these codes to go through the RUC code review process rather than identifying the codes as potentially misvalued through this screen.

Response: Although a number of codes have been or will be considered through the RUC review process, until we receive recommendations and review the codes for both work and direct PE inputs, we will continue to include these codes on the high expenditure list. We reiterate that we do not believe that the presence of a code on a misvalued code list signals that a particular code necessarily is misvalued. Instead, the lists are intended to prioritize codes to be

reviewed under the misvalued code initiative. If any code on the list finalized here is already being reviewed by the RUC through its process, we will receive a recommendation regarding valuation for the code, and the presence or absence of the code in this particular list is immaterial. However, if subsequent to the removal of a code from the high expenditure code list, the RUC decides not to review the code, we would still want to consider the code as potentially misvalued based on its meeting the criteria established for the screen. Therefore, we do not agree that we should remove individual codes from a potentially misvalued code list because the RUC already anticipates reviewing the code. However, we want to be clear that when we receive RUC recommendations regarding a code, we generally remove that code from misvalued code lists, regardless of whether or not the RUC reviewed the code on the basis of that particular screen.

Accordingly, we are finalizing the 103 codes in Table 8 as potentially misvalued services under the high expenditure screen and seek recommended values for these codes from the RUC and other interested stakeholders.

TABLE 8: List of 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/>
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
36215	Place catheter in artery
36556	Insert non-tunnel cv cath

HCPCS	Short Descriptor
36569	Insert picc cath
36620	Insertion catheter artery
38221	Bone marrow biopsy
51700	Irrigation of bladder
51702	Insert temp bladder cath
51720	Treatment of bladder lesion
51784	Anal/urinary muscle study
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
77059	Mri both breasts
77263	Radiation therapy planning
77334	Radiation treatment aid(s)
77470	Special radiation treatment
78306	Bone imaging whole body
88185	Flowcytometry/tc add-on
88189	Flowcytometry/read 16 & >

HCPCS	Short Descriptor
88321	Microslide consultation
88360	Tumor immunohistochem/manual
88361	Tumor immunohistochem/comput
91110	Gi tract capsule endoscopy
92136	Ophthalmic biometry
92240	Icg angiography
92250	Eye exam with photos
92275	Electroretinography
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
93351	Stress tte complete
93503	Insert/place heart catheter
93613	Electrophys map 3d add-on
93965	Extremity study
94620	Pulmonary stress test/simple
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 snpl 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

HCPCS	Short Descriptor
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

6. 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 the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the procedure. For these diagnostic and therapeutic procedures, only the procedure code is reported by the practitioner who conducts the procedure, without separate billing by the same practitioner for anesthesia services, and, in developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation. 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 appropriate. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared 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, broad-based information about the provision of moderate sedation, 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 code 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 to which each code may be misvalued. 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 involved in these services 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, in the CY 2016 PFS proposed rule, we solicited recommendations from the RUC and other interested stakeholders on the 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, in the CY 2016 PFS proposed rule, we proposed to identify CPT codes 00740 and 00810 as potentially misvalued. We welcomed comments on both of these issues.

Comment: Several commenters noted that they support CMS' decision to seek input from the medical community prior to proposing a method for reporting and valuing moderate sedation as well as adjusting existing valuations to remove these services. One commenter also encouraged CMS to seek and consider recommendations from societies that represent members who provide dialysis vascular access interventional care, such as the American Society of Diagnostic and Interventional Nephrology.

Response: We thank the commenters for their support. Through notice and comment

rulemaking, we will review and consider any recommendations from the public, including those from any interested specialty societies.

Comment: In response to CMS' proposal to identify anesthesia procedure codes 00740 and 00810 as potentially misvalued, the RUC stated that the committee anticipated reviewing CPT codes 00740 and 00810 as potentially misvalued codes.

Response: We appreciate the RUC's responsiveness to the proposal.

Comment: One commenter disagreed that the increase in utilization of anesthesia is indicative of potential misvaluation of the codes in Appendix G. This commenter noted that the policy adopted by CMS in the CY 2015 final rule to eliminate cost-sharing for anesthesia furnished in conjunction with screening colonoscopies encourages patients to undergo these screenings. The commenter also noted that use of anesthesia with upper endoscopy procedures not only decreases patient discomfort, but also decreases complications and creates more optimal conditions for efficiency during the procedure as well as reduced recovery time as compared to the use of narcotics and sedative hypnotic agents. The commenter believes that this results in savings that offset the costs of anesthesia services. The commenter also expressed the view that the work involved in these services has not changed.

Response: We thank the commenters for their input. Since the pool of beneficiaries that receive anesthesia in conjunction with these Appendix G services has grown, we believe it is possible that the typical circumstances under which patients receive these services have changed since the services were last reviewed. Therefore, we continue to seek recommendations regarding appropriate approaches to valuation for these services.

Comment: A few commenters noted that there are a variety of services in Appendix G and stated their view that practitioners who furnish services for which there are claims data supporting the inherent nature of moderate sedation should not have to report moderate sedation separately, as they believe they would be faced with administrative burden and costs. They

recommended that CMS conduct ongoing analysis of claims data to determine which codes may require unbundling of moderate sedation and to refer only those codes as potentially misvalued. One commenter noted that they opposed the use of any “blanket approach” to valuing moderate sedation such as removing the standard packages for the direct PE inputs associated with moderate sedation. The commenter recommended instead that we look at codes by family or specialty in order to ensure that reimbursements are fair and accurate. One commenter also noted the difference in the work involved with moderate sedation when it is furnished by the same physician who is furnishing the procedure compared with when it is furnished by another clinician, and requested that this be considered when valuing the moderate sedation services. Another commenter suggested that CMS create a modifier to be used by surgeons providing moderate sedation. They also suggested that CMS consider the expenses involved with using a registered nurse or CRNA, the medications and delivery systems, patient monitoring equipment, and lengthened postoperative recovery period when valuing moderate sedation services.

Response: We thank the commenters for their input. We will consider input from the medical community on this issue through evaluation of CPT coding changes and associated RUC recommendations, as well as feedback received through public comments, as we value these services through future notice and comment rulemaking.

7. 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 periods in order to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre- and postoperative visits and the surgical procedure itself. Although in previous rulemaking we have marginally addressed some of the concerns we identified with global packages, we believe there is still a need to address other fundamental issues with the 10- and

90-day postoperative global packages. We believe it is critical that the RVUs we use 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.

In the rulemaking for CY 2015, 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 postoperative 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 postoperative physicians' services in the 0-day global code; 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 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 that 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 sought input from stakeholders on various aspects of this task. We solicited 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 postoperative periods) needed to increase the accuracy of the values for surgical services. We also solicited comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the postoperative period, and how we might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019.

We received many comments regarding the kinds of auditable, objective data needed to increase the accuracy of the values for surgical services and the most efficient means of acquiring these data. Commenters had several suggestions for the approach that CMS should take, including the following:

- Collect and examine large group practice data for CPT code 99024 (postoperative follow-up visit).
- Review Medicare Part A claims data to determine the length of stay of surgical services performed in the hospital facility setting.
- Prioritize services that the Agency has identified as high concern subjects.
- Review postoperative visit and length of stay data for outliers.

In general, commenters were supportive of the need to identify auditable, objective, representative data, but many were not able to identify a specific source for such data. We appreciate the comments we received and we will consider these suggestions for purposes of future rulemaking.

As noted above, section 1848(c)(8)(C) of the Act mandates that we use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. We described in 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 sought public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and postoperative care, including the follow-up care during postoperative days. We were also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during postoperative care.

We received many comments regarding potential methods of valuing the individual components of the global surgical package, including the following:

- Use a measured approach to valuing the individual components of the global surgical package rather than implementing a blanket data collection policy.
- Examine and consider the level of the postoperative E/M visits, including differences between specialties.
- Consider the interaction between the valuing the global surgery package and the multiple procedure payment reduction (MPPR) policy.

We will consider these comments regarding the best means to develop and implement the process to gather information needed to value surgical services and will provide further opportunity for public comment through future rulemaking.

Comment: We received many comments expressing strong support for the CMS proposal to hold an open door forum or town hall meetings with the public.

Response: We appreciate the extensive comments we received from the public regarding the global surgical package. We have noted the positive feedback from commenters about holding potential open forums or town hall meetings to discuss this process. We will consider these

comments regarding the best means to develop and implement the process to gather information needed to value surgical services as we develop proposals for inclusion in next year's PFS proposed rule.

C. Elimination of the 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 RVUs 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

We proposed to permanently eliminate the refinement panel beginning in CY 2016, and instead, publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. For example, we would 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 were published in the CY 2016 PFS proposed rule. As explained in the CY 2015 final rule with comment period, a smaller 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. Under our proposal, 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 <http://www.regulations.gov>. We welcomed comments on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

The following is a summary of the comments we received on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

Comment: The majority of commenters, including the American Medical Association/Specialty Society Relative (Value) Update Committee, opposed the proposal to

eliminate the refinement panel. Commenters expressed concern that the complete elimination of the refinement process decreases CMS's accountability to its stakeholders who do not agree with the Agency's decisions. They urged CMS to provide detailed guidance on how to seek a change in previously finalized RVUs including the process to initiate a meeting with CMS staff to share and discuss new information or clarify previously shared information, as well as any key timelines or dates that may impact CMS's ability to initiate a change in previously finalized RVUs. Commenters also urged CMS to maintain a transparent appeal process. Another stated that, as CY 2017 will be the first full year using the new process for establishing final values for interim final codes, it is possible that unforeseen needs for the continuation of the refinement panel could arise.

Several commenters agreed with the proposal to eliminate the refinement panel. One commenter supported the permanent elimination of the refinement panel since CMS's display of interim final values in the subsequent year's proposed rule will provide another opportunity for public input. Another believed the new process will provide more timely input on the codes and stated that publishing interim final values for these in the proposed rule versus the final rule should allow adequate time for public comment and for physicians to prepare for changes that would have an impact on their practices and patients. Another commenter welcomed the increased opportunity to review and comment on interim values, especially given that CMS has not been obligated to accept recommendations of the refinement panels and has frequently rejected those recommendations.

Response: We appreciate all of the comments on the proposal. We understand that commenters have an interest in a transparent process to review CMS's assignment of RVUs to individual PFS services. We also understand that some commenters believe that the purpose of the refinement panel process is to provide for reconsideration of the agency's previous decisions. However, the refinement panel was established to assist us in reviewing the public comments on

CPT codes with interim final work RVUs and in balancing 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. Therefore, we do not believe that the refinement panel has generally served as the kind of “appeals” or reconsideration process that some stakeholders envision in their comments. We also have come to believe that the refinement panel is not achieving its intended purpose. Rather than providing us with additional information, balanced across specialty interests, to assist us in establishing work RVUs, the refinement panel process generally serves to rehash the issues raised and information already discussed at the RUC meetings and considered by CMS.

We also appreciate commenters’ interest in CMS maintaining a transparent process with public accountability in establishing values for physicians’ services. In contrast to the prior process of establishing interim final values and using a refinement panel process that generally is not observed by members of the public, we believe that the new process of proposing the majority of code values in the proposed rule and making sure that those proposed values are open for comment prior to their taking effect for payment inherently represents greater transparency and accountability. We will also continue to work towards greater transparency in describing in rulemaking how we develop our proposed values for individual codes. We believe that focusing our resources on notice and comment rulemaking would facilitate greater transparency.

Given that the timing for valuation of PFS services under the new process will in large part mitigate the need to establish values on an interim final basis and will provide two opportunities for notice and public comment, we do not believe that the refinement panel would necessarily provide value as an avenue for input, for either CMS or stakeholders, beyond that intrinsic in the notice and comment rulemaking process. However, we appreciate commenters’ concerns that the new process has not been fully implemented and there may be unanticipated needs for additional input like the kind made available through the refinement panels. We agree

that it may be advisable to preserve existing avenues for public input beyond the rulemaking process, like the refinement panel.

Therefore, after consideration of all of the comments and the issues described in this section, we are not finalizing our proposal to eliminate the refinement panel process at this time. Instead, we will retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. We will make the determination on whether to convene refinement panels on an annual basis, based on review of comments received on interim final values. We remind stakeholders that CY 2016 is the final year for which we anticipate establishing interim final values for existing services.

We also want to remind stakeholders that we have established an annual process for the public nomination of potentially misvalued codes. This process, described in the CY 2012 PFS final rule (76 FR 73058), provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention.

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

In the CY 2016 PFS proposed rule, we sought public comment on a number of issues regarding payment for primary care and care coordination under the PFS. 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) model, 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 and 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 qualifying 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 our comment solicitation and the public comments we received regarding 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. Commenters stated that the time and intensity of the cognitive efforts associated with such planning 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 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, in the CY 2016 PFS proposed rule we solicited 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. To appropriately recognize the different resource costs for this additional cognitive work within the structure of PFS resource-based payments, we

were particularly interested in codes that could be used in addition to, not instead of, the current E/M codes.

In our comment solicitation, we stated that, 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 E/M 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 stated that we were 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 were 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipated using an approach similar to our multi-year approach for implementing CCM and TCM services, to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

Comment: We received many comments on these potential policy and coding refinements that will be useful in the development of potential future policy proposals. We note that the American Medical Association and others urged us to make separate Medicare payment for existing CPT codes that are not separately paid under the PFS, but that describe similar services and for which we have RUC-recommended values. These codes describe a broad range of services, some of which involve non face-to-face care management over a period of time.

Response: We will take the comments into consideration in developing any potential policy proposals in future PFS rulemaking.

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 includes payment 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, in the CY 2016 PFS proposed rule we also sought 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 were 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 expressed interest 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 were 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 under the PFS. We also expressed interest 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 solicited comments 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 solicited comments 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipated using an approach similar to our multi-year approach for implementing CCM and TCM services, to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

Comment: We received many comments on these potential policy and coding refinements that will be useful in the development of potential future policy proposals.

Response: We will take the comments into consideration in developing any potential policy proposals in future PFS rulemaking.

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, in the proposed rule, we were particularly interested in comments 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 would evaluate potential refinements to the PFS to account for the provision of services through such a model. We solicited information to assist us in considering refinements to coding and payment to address this model in particular. We also sought comments on the potential application of the collaborative care model for other diagnoses and treatment modalities. For example, we solicited 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 requested 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 comment solicitation on interprofessional consultation, since the patient may not have direct contact with the psychiatric consultant we solicited comments 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 also solicited comments 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.

In addition, we solicited comments on whether this kind of care model should be implemented through a CMMI model 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017.

Comment: We received many positive comments regarding the possibility of implementing new payment codes that would allow more accurate reporting and payment when these services are furnished to Medicare beneficiaries.

Response: We appreciate commenters' interest in appropriate coding and payment for

these services. We will take all comments into consideration as we consider the development of proposals in future rulemaking.

We took particular note that several commenters identified resource inputs CMS might use to value these services under the PFS, including defined time elements. As we consider those comments, we encourage stakeholders to consider whether there are alternatives to time elements that would account for the range in intensity of services delivered in accordance with beneficiary need. In addition, since the collaborative care models described in the proposed rule include primary care-based care management, as well as psychiatric consulting, we encourage further input including comments on this final rule with comment period, from a broad group of stakeholders, including the community of primary care providers, who are critical in the successful provision of these services.

3. CCM and TCM Services

a. Reducing Administrative Burden for CCM and TCM services

In CY 2013, we implemented separate payment for TCM services under CPT codes 99495 and 99496, and in CY 2015, we implemented separate payment for CCM services under CPT code 99490. We established many service elements and billing requirements that the physician or nonphysician practitioner must satisfy to fully furnish these services and to report these codes (77 FR 68989, 79 FR 67728). Particularly because of the significant amount of non face-to-face work involved in CCM and TCM services, these elements and requirements were relatively extensive and generally exceeded 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 solicited 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. In the CY 2016 PFS proposed rule, we solicited stakeholder input on how we could 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 recognized 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 sought information regarding the circumstances under which CCM services are furnished. This information would include 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 were interested in examining such information 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 also solicited objective data regarding the resource costs associated with furnishing the services described by this code. We stated that as we review that information, in addition to our own claims data, we would 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.

Comment: We received several comments recommending various changes in the billing requirements for CCM and TCM services. Some commenters sought significant changes to the CCM scope of service elements, such as eliminating the requirement to use certified electronic health record technology (CEHRT); suspending the electronic care plan sharing requirement until such time that electronic health records (EHRs) have the ability to support such capabilities; or having CMS provide a model patient consent form. Other commenters recommended more minor changes such as clarifying the application of CCM rules regarding fax transmission from certified EHRs, and changing the reporting rules for TCM services (required date of service and when the claim can be submitted). Many commenters stated the current payment amounts are not adequate to cover the resources required to furnish CCM or TCM services and urged CMS to increase payments, for example by creating an add-on code to CPT code 99490, increasing the clinical labor PE input for CPT code 99490 to the RUC recommended 60 minutes, and/or paying separately for the complex CCM codes (CPT codes 99487 and 99489). Commenters also noted that since CY 2015 is the first year of separate payment for CCM, there is little utilization data available to assess average time spent in furnishing CCM services and similar issues. One commenter planned to share data with CMS next spring upon completion of a study on the cost and value associated with care management.

Response: We will take these comments into consideration in the development of potential proposals for future PFS rulemaking. We will develop subregulatory guidance clarifying the intersection of fax transmission and CEHRT for purposes of CCM billing. Regarding TCM services, we are adopting the commenters' suggestions that the required date of service reported on the claim be the date of the face-to-face visit, and to allow (but not require) submission of the claim when the face-to-face visit is completed, consistent with current policy governing the

reporting of global surgery and other bundles of services under the PFS. We will revise the existing subregulatory guidance for TCM services accordingly.

E. 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)(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 estimated net reduction in expenditures for a year as a result of adjustments to the relative values for misvalued codes is equal to or greater than the target for that year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met for that subsequent year. Section 1848(c)(2)(O)(iv) of the Act defines a target recapture amount as the difference between the target for the year and the estimated net reduction in expenditures under the PFS resulting from adjustments to RVUs for misvalued codes. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. Section 220(d) of the PAMA applies to calendar years (CYs) 2017 through 2020 and sets 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 the CY 2016 PFS proposed rule, we proposed 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 identified several aspects of our approach for which we specifically solicited comments. We organized this discussion by identifying and explaining these aspects in particular but we solicited comments 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 updated 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 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.H.2. of this final rule with comment period, 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 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 generates challenges in 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 final rule with comment period, we are finalizing values for a significant portion of misvalued codes during one calendar year. Therefore, CY 2015 will include a significant 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 proposed 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 changes for CY 2016 included under this definition of “adjustments to RVUs for misvalued codes” is available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>

The following is a summary of the comments we received regarding this aspect of the proposal to implement the statutory provision:

Comment: Several commenters, including the RUC, supported CMS’ proposal to include all services that receive revised input values even if the specific codes were not identified on a misvalued services list for review; the commenters’ stated that this is a reasonable and fair approach.

Response: We appreciate the commenters’ feedback and support.

Comment: A few commenters stated that the selection of codes to be included for review beyond the codes identified by the screens should be determined by the pertinent specialty societies as they are the best determiners of which codes make up a family of codes. Another commenter stated that CMS should include the E/M services in the list of codes that are potentially misvalued.

Response: We note that the process for selection of codes to be reviewed as potentially misvalued is addressed in section II.H. of this final rule with comment period and has also been

addressed in prior rulemaking. Our proposal to implement section 1848(c)(2)(O) of the Act does not address how codes are identified to be reviewed under the misvalued code initiative. Instead, it addresses how to identify the changes in expenditures that result from such reviews in the calculation of the target amount.

Comment: Several commenters, including the RUC, also supported CMS' proposal to exclude code level input changes for CY 2015 interim final values from the calculation of the target. The commenters concur that the year 2 and year 3 changes in values represent an incomplete picture of the redistributive effects for a particular year resulting from the review of the misvalued services, and the vast majority of redistribution happens between year 1 and year 2.

Response: We appreciate the commenters' support and feedback.

Comment: One commenter disagreed with CMS' proposal to exclude code-level input changes for 2015 interim final values stating that it means organized medicine does not get credit for any net decreases associated with such codes and is therefore being penalized. The commenter requested that CMS consider including 2015 interim final values in the calculation of the 2016 misvalued code target even though the misvalued change occurred over multiple years. Another commenter stated that the proposed net reduction in expenditures of 0.25 percent, as opposed to 1.00, means that the 0.75 percent difference will come from the conversion factor, and doing so would more than negate the 0.5 percent increase physicians were promised under MACRA, and therefore the commenter requested that CMS help mitigate this result by including 2015 interim final values in the calculation of the target.

Response: With regard to the commenters who disagreed with the exclusion of code-level input changes for 2015 interim final values, we cannot determine if the commenters intended to suggest that CMS was not including decreases that would help towards the achievement of the misvalued code target by excluding changes for 2015 interim final values, or

that CMS should include the changes between years 1 and 3. As stated in the CY 2016 proposed rule (80 FR 41712 through 41713), 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 code values 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). Additionally, the statute requires comparison between 2 years, and therefore, we do not believe we have the authority to include changes between year 1 and year 3. Since our remaining options were to include changes between year 2 and year 3 which, as indicated above, generally results in an increase, or to exclude code-level input changes for CY 2015 interim final values, and the commenters express interest in moving closer to achievement of the target, we do not believe it would be in the commenters' interest to include the changes between years 2 and 3.

With regard to the commenter who stated that the net reduction in expenditures under the PFS if CMS does not achieve the target reduction would negate the 0.5 percent increase physicians were promised under MACRA, we note that both of these provisions continue to apply under current law.

Comment: Some commenters, including the RUC, suggested that CMS should be sure to include existing codes that are either being deleted or will have utilization changes as a result of the misvalued code project and/or the CPT Editorial Panel process. Another commenter stated that CMS was excluding existing codes with large volume changes, and recommended that such codes be included in the calculation of the target. Some commenters recommended that CMS conduct a procedure-to-procedure comparison and then calculate the net reduction in RVUs, including the values of new and deleted CPT codes prompted by the misvalued code initiative. The commenters stated that this is an area where the specialty societies and CMS need to work together to determine the comparisons for calculating the net reduction.

Response: We agree that changes in coding often contribute to improved valuation of PFS services. We note that we included these changes in our methodology in the proposed rule and explained that we would include services directly affected by changes to coding for related services. We did not propose to exclude existing codes with large volume changes; changes for such codes have been included. To clarify, we are including changes in values for any codes for which changes in coding or policies may result in differences in how a given service is reported from one year to the next. Under our current ratesetting methodologies, we already consider how coding revisions change the way services are reported from one year to the next. The crosswalk we use to incorporate such changes in our methodology is based on RUC and specialty society recommendations that explicitly address the kinds of procedure-to-procedure comparisons suggested by the commenter. This file is available in the “downloads” section of the PFS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html> under “Analytic Crosswalk from CY 2015 to CY 2016.” Since it reflects the best information available, we used the same crosswalk to account for coding changes in the calculation of the target. We also refer readers to the list of HCPCS defined as misvalued for purposes of the target which is available on the CMS web site under downloads for the CY 2016 PFS final rule with comment period.

Comment: One commenter recommended that CMS include the review of all individual codes and broader adjustments across the PFS, as this would more accurately represent the total revaluations.

Response: As we explained in the proposed rule, our goal is to include the review of all individual codes and changes to inputs for additional codes where changes can be measured between two years. Because PFS payments are developed under the statutory requirements of relativity and budget neutrality, including all adjustments to all codes would necessarily result in a net of zero.

Comment: A few commenters raised objections to the statutory provision. For example, one commenter stated that the legislation is penalizing physicians and other healthcare professionals for already having taken on the task of identifying and revaluating potentially misvalued codes over the past 10 years. Other commenters stated that since the RUC and specialty societies have been addressing potentially misvalued codes since 2006, there should be a way to include revaluations made back to 2006 in the calculation of the target. Another commenter stated that CMS should hold primary care and E/M services harmless in this process, since these services are not over-valued but rather under-valued. One commenter requested more time to evaluate the proposed process to identify yearly targets, and encouraged CMS to work with the AMA to discuss this issue at future RUC Panel meetings prior to implementing the provision. One commenter requested that CMS review its approach to determine if there are other methods that will come closer to reaching the target. One commenter stated that this new requirement creates a potential incentive to target codes that offer the greatest likelihood of savings, not those that are actually misvalued.

Response: We appreciate the commenters' feedback and have considered these concerns to the extent possible in light of the requirements of section 1848(c)(2)(O) of the Act.

After consideration of the public comments received, we are finalizing the approach of defining 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, including any codes for which changes in coding or policies might result in differences in how a given service is reported from one year to the next. We are also finalizing our proposal to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target. After considering all comments, we continue to believe this approach is appropriate and compliant with statutory directives.

2. Calculating "Net Reduction"

Once the RVU adjustments attributable to misvalued codes are identified, estimated net reductions in PFS expenditures resulting from those adjustments would be calculated by determining the sum of all decreases and offsetting them against any applicable increases in valuation within the changes that we defined as misvalued, as described above. Because section 1848(c)(2)(O)(i) of the Act only explicitly addresses reductions in expenditures, and we recognize that 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 proposed 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.

The following is a summary of the comments we received regarding our proposal.

Comment: One commenter stated that the proposal for calculating net reduction is consistent with the plain reading of the statute.

Response: We appreciate the commenter's feedback and support.

Comment: Several commenters, including the RUC, requested that CMS use a more transparent process for calculation of the target, suggesting that the discussion in the CY 2016 PFS proposed rule was not sufficiently detailed to allow for replication by external stakeholders. Commenters requested that CMS provide a comprehensive methodological description of how CMS will calculate the target, including publication of dollar figure estimates, and information about individual service level estimated impacts on the net reduction. Commenters further requested that we provide the impact on the net reduction either per CPT code, or that we identify a family of services and publish a combined impact for that family. Another commenter expressed concern with how CMS will operationalize this policy, noting that the language in the CY 2016 PFS proposed rule did not outline where the adjustments would be made. The commenter further questioned how CMS planned to track the "savings" from the revaluation of services, and requested that CMS clarify how new technology will be handled, as well as new codes that are a restructuring of existing codes.

Response: We appreciate the commenters' feedback. In response to the request for greater transparency, we have posted a public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS website under the supporting data files for the CY 2016 PFS final rule at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

In response to the commenter who asked for clarification on how new technology will be handled, we assume the commenter intends to ask about how new codes for new services would be addressed under our proposed methodology. Under our proposal, we would include

adjustments to values for all deleted, new, and revised codes under our calculations of changes from one year to the next. We would also weight the changes in the values for those codes by the utilization for those services in order to calculate the net reduction in expenditures. If a new code describes a new service (new technology as opposed to recoding of an existing service), then there would be no utilization for that code in the calculation. Without utilization, the value for a new service would have no impact on the calculation of the target. In response to the commenter who expressed concern about how CMS would operationalize this policy, and stated that CMS did not explain where the adjustments would be, we note that if the estimated net reduction in expenditures is less than the target for the year, then there would be an overall reduction to the PFS conversion factor as described in section VI. of this final rule with comment period.

Comment: One commenter disagreed that all increases should be incorporated into the net reduction calculation and requested that CMS consider an approach that would maximize the overall magnitude of the measured reductions in order to prevent an overall reduction to the PFS conversion factor as a result of failure to achieve the target for reductions. Specifically, the commenter stated that codes identified as potentially misvalued for which there is compelling evidence based on the RUC recommendations to support an increase in RVUs based on a change in work should not be defined as misvalued for the purposes of calculating the target.

Response: We believe the requirement that we calculate the net reduction in expenditures indicates that we must account for adjustments in values including both increases and decreases and therefore, believe our proposal comports with the plain reading of the statute. We recognize that the RUC internal deliberations include rules that govern under what circumstances individual specialties can request that the RUC recommend CMS increase values for particular services. As observers to the RUC process, we appreciate having an understanding of these rules in the context of our review of RUC-recommended values. However, we do not

believe that the internal RUC standards for developing recommendations are relevant in determining whether the statutory provision applies to adjustments to values for individual codes.

Comment: Some commenters requested that CMS review its administrative authority to achieve a target recapture amount in a selective manner, rather than by an across-the-board adjustment to the conversion factor. A commenter stated that codes already sustaining reductions in 2016, and consequently contributing to the target, should not be subjected to additional across-the-board cuts to achieve the statutory target.

Response: We do not believe that section 1848(c)(2)(O)(iii) of the Act provides us authority to insulate particular services from the effects of the budget neutrality adjustment for the target recapture amount that is required if the estimated net reduction in expenditures is less than the target for the year. The statute specifies that an amount equal to the target recapture amount is not to be taken into account in applying the PFS budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. This PFS budget neutrality adjustment has been in place since the outset of the PFS, and we have consistently interpreted and implemented it as an adjustment that is made across the entire PFS. Therefore, we do not believe we can apply the budget neutrality adjustments in a selective manner.

Comment: Several commenters, including the RUC, stated that when considering the net impact of service-level input changes in a given year, it is important for CMS to understand specific scenarios in which codes under review should not be included in the net reduction target calculation. The commenters requested that CMS not include particular payment initiatives, such as Advance Care Planning (ACP), in the target definition. Instead, since the payment rates for these services require budget neutrality and relativity adjustments to all other PFS services and these reductions are not otherwise accounted for in the target calculation, CMS should count the payments for ACP services as “redistribution” (or, in other words, reductions) from other

services for CY 2016. Commenters urged CMS to use the same approach for care management services valued under the PFS in the future. Generally, the commenters stated that these and similar new codes could not possibly be misvalued and therefore, should not only be excluded from the target, but the reductions to other services due to separate payment for these services should be counted as net reductions toward achievement of the misvalued code target.

Response: Because we believe that all of our intended revaluations of services under the PFS are intended to improve the accuracy of the relative value units for PFS services, we do not believe we should exclude increases and decreases to particular services in the target calculation. Therefore, we do not agree with commenters' suggestions that codes describing one kind of service (e.g. care management) as opposed to another (for example, procedures or diagnostic tests) should be excluded from the target under the statutory provision. Similarly, we do not agree that counting the relativity and budget neutrality redistributions that result from care management services as part of the net "reduction" would be consistent with a reasonable understanding of "net reduction" in allowed expenditures as a result of changes to misvalued codes.

However, in considering the points raised by commenters, we do agree that the increases in value for new codes like ACP or Chronic Care Management (CCM) are not the same as increases to other services. In general, new codes describe new services that would not have been reported with particular codes in the previous years or new codes describe existing services that were reported using other codes in the prior year. In other cases, however, new codes describe services that were previously included in the payment for other codes. When those services become separately payable through new codes, we generally make adjustments to other relevant codes to adjust for the value of the services that will be separately reported. In general, new codes describing care management services fall into this latter category, since the associated resource costs for these services were previously bundled into payment for other services.

However, unlike many other PFS services, the resource costs for these kinds of services were bundled into a set of broadly reported E/M codes and services that include E/M visits. Since these codes are so broadly reported across nearly all PFS specialties, to the extent that it would be impracticable to make adjustments to individual codes, we have not made corresponding adjustments to E/M visits to account for the status of the new codes as separately billable. Instead, when unbundling new separately reported services such as these, we have allowed our general budget neutrality adjustment to account for these types of changes, since budget neutrality adjustments apply broadly to the full range of PFS services, including both codes that specifically describe E/M visits and those with E/M services as components of the service, such as all codes with global periods. In terms of calculating the net reduction in expenditures for purposes of section 1848(c)(2)(O)(i) of the Act, this means that the shift in payment to these new separately reportable services, unlike the adjustments to values for other new services, is not offset by adjustments to any other individual codes. Therefore, under the methodology we proposed, the increase in payment for these new separately reportable services would be counted in the net reduction calculations since the adjustments to values for these services are reflected in values for individual codes, but the corresponding decreases would not be counted, since the corresponding decreases are not attributable to any particular codes. Under the methodology we proposed, the change to make these types of codes separately reported would be counted against achievement of the target even though the increases in value for these codes are fully offset by budget-neutrality adjustments to all other PFS services.

As we have reflected on the comments and on this particular circumstance, we do not believe that the change to separate payment for these kinds of services should be counted as increases that are included in calculating the “net reductions” in expenditures attributable to adjustments for misvalued codes. Instead, we think that the adjustments to value these services should be considered in the context of the budget neutrality adjustments that are applied broadly

to PFS services. This would be consistent with our treatment of the increase in values for other new codes since the reductions or deletion of predecessor codes are counted as offsets in our calculation. Since, under the established ratesetting methodology, the increases in new separately reportable services and the corresponding budget neutrality decreases fully offset one another and net to zero, we believe that the easiest way to account for the adjustments associated with valuing these services is to exclude altogether the changes for these types of codes from the list of codes included in the target. This will effectively make the creation and valuation of such codes neutral in the calculation of the misvalued code target.

After considering public comments, we are finalizing our policy as proposed with a modification to exclude from the calculation of the “net reduction” in expenditures changes in coding and valuation for services, such as ACP for CY 2016, that are newly reportable, but for which no corresponding reduction is made to existing codes and instead reductions are taken exclusively through a budget neutrality adjustment.

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 had the advantage of being intuitive and readily replicable.

However, there are several issues related to the potential imprecision of this method. 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. Although we believe that this approach would be transparent and external stakeholders could replicate this method, it might be difficult and time-consuming for stakeholders to do so. We also noted that when we modeled the interaction of the statutory phase-in requirement under section 220(e) of the PAMA 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 years, we found that both approaches generally resulted in similar estimated net reductions. After considering these options, we proposed to use the simpler 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 solicited comments 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.

The following is a summary of the comments we received regarding our proposal.

Comment: A few commenters supported CMS' selection of the simpler formula to calculate the target over the more precise but more complex formula since it is simpler and easier to understand. One commenter stated that CMS did not indicate exactly how similar the two proposals are or which method estimated the larger reduction, and stated that CMS should make this information available in the final rule and consider revising the approach in CY 2017 rulemaking and use the method that results in the larger reduction.

Response: We do not agree that CMS should do both calculations and determine which to use based solely on which results in the higher amount. We note that the target for net reductions in expenditures from adjustments to values for misvalued codes is a multi-year provision and we believe neither of the two methodologies is assured to produce a consistently higher result from year to year. Since the majority of commenters agree that the more intuitive approach to estimating the net reduction in expenditures is preferable to the more precisely accurate approach, we are finalizing our approach as proposed.

Comment: One commenter requested that CMS count the full reduction in payment for codes subject to the phase-in required under section 1848(c)(7) of the Act as discussed in section II.F. of this final rule with comment period, toward the target in the first year. Another commenter stated that CMS used the fully reduced RVUs in calculating the target, not the first year phase-in RVUs, and therefore, CMS should include the full impact of the change in the equipment utilization rate for linear accelerators toward the target calculation. Similarly, the commenter requested that any future multi-year phase-in proposals should similarly be counted toward the target in the first year.

Response: The target provision requires the calculation of an estimated net reduction measure between 2 years of PFS expenditures. As we have detailed in the above paragraphs, we believe that under certain specific circumstances, changes should be excluded from that estimate; but we do not believe we can include changes that would occur in future years based solely on

the rulemaking cycle during which policies are established. Therefore we will not count the full reduction in payment for codes that are subject to the phase-in toward the calculation of the net reduction in expenditures for the first year. With regard to the commenter that stated that CMS used the fully reduced RVUs in calculating the target, we note that we only used the first year phase-in RVUs and, for the reasons stated above, believe that we are limited to including only the changes in the immediate year in the calculation of the target.

After consideration of the public comments received, we are finalizing the policy to calculate the net reduction using the simpler method as proposed.

4. Target Achievement for CY 2016

We refer readers to the regulatory impact analysis section of this final rule with comment period for our final estimate of the net reduction in expenditures relative to the 1 percent target for CY 2016, and the resulting adjustment required to be made to the conversion factor.

Additionally, we refer readers to the public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>.

F. 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 the CY 2016 PFS proposed rule, we proposed a methodology to implement this statutory provision. In developing this methodology, we identified several aspects of our approach for which we specifically solicited comments, given the challenges inherent in implementing this provision in a manner consistent with the broader statutory construct of the PFS. We organized this discussion by identifying and explaining these aspects in particular but we solicited comments on all aspects of our proposal.

1. Identifying Services that are Not New or Revised Codes

As described in this final rule with comment period, 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 changes to RVUs that occur as a result of a coding change for a particular service over 2 years 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 proposed 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 excludes 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 also are excluding 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 application of the phase-in is also 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 also excluded 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.

We received few comments regarding this aspect of our proposal, and some of the comments suggested changes that would require changes to the statutory provision that requires the phase-in of significant changes in RVUs. The following is a summary of the comments that we received.

Comment: One commenter agreed with CMS' broad definition of new or revised.

Response: We appreciate the commenter's feedback and support.

Comment: One commenter did not agree that new and revised services should be excluded from the phase-in, and suggested that the phase-in be applied more broadly.

Response: Section 1848(c)(7) of the Act specifies that services described by new or revised codes are not subject to the phase-in of significant reductions in RVUs. Additionally,

because RVUs are assigned to individual codes, we do not believe there would be a straightforward or transparent way to phase in reductions for services that are described by new or revised codes between the years for which a phase-in would apply.

Comment: One commenter urged CMS to include in the phase-in codes that had interim final values for CY 2015 and have substantial reductions of 20 percent or greater as compared to the 2014 values.

Response: We do not believe it would be consistent with the statutory provision to phase in changes in values between 2015 and 2016 based on 2014 values. Section 1848(c)(7) of the Act, as amended, specifies that the phase-in of significant reductions in values begins for fee schedules established beginning with 2016.

Comment: One commenter stated that any code that has a decrease in value of over 20 percent due to repricing of expensive supplies (for example, over \$500) should be excluded from the phase-in provision.

Response: We appreciate the commenter's feedback and understand the rationale for the request; however, we do not believe that we have the discretion to exempt codes from the phase-in, regardless of the reason for the reduction.

After consideration of the public comments received on this aspect of our proposal to implement the phase-in of significant changes in RVUs, we are finalizing the implementation of the phase-in for significant (20 percent or greater) reductions in RVUs as proposed.

2. Estimating the 20 Percent Threshold

Because the phase-in of significant reductions in RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we proposed 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.

The following is a summary of the comments we received regarding this proposal.

Comment: One commenter supported CMS' proposal for estimating the 20 percent threshold.

Response: We appreciate the commenter's support.

Comment: Another commenter did not agree with the proposal to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. The commenter stated that the methodology should not give inequitable treatment to any particular specialty, and instead it should apply to all codes that are cut greater than 20 percent in the final analysis.

Response: We appreciate that our proposed methodology could, in the end, result in no phase-in for some codes that ultimately do have a 20 percent or greater reduction in value after application of required budget neutrality adjustment. However, we have no reason to believe that this situation, resulting from using initial unadjusted RVUs to identify significant RVU reductions, would disadvantage one specialty more than the next. Therefore, we also do not believe that our proposed approach is likely to result in unequitable treatment to any one specialty over another.

After consideration of the public comments received on this aspect of our proposal, we are finalizing without modification our proposal to identify significant reductions in RVUs based on a comparison of RVUs before application of budget neutrality adjustment.

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 not take place in the first year of the phase-in.

After considering both of these options, we proposed 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 solicited comments on this proposal.

The following is a summary of the comments we received regarding this proposal.

Comment: Several commenters supported CMS' proposal 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.

Response: We appreciate the commenters' feedback and support.

Comment: Several commenters did not support CMS' proposal, and instead stated that CMS should spread the transition evenly over both years—meaning a 50 percent phase-in for year one and year two. One commenter stated that this would lead to a more equitable payment system and allow physicians more time to make changes in their practices to accommodate for reductions. Another commenter acknowledged that codes with reductions that are less than 20 percent and not phased-in may experience greater reductions in the first year, however the commenter stated that a more gradual phase-in for practices facing steeper cuts should be the paramount principle for any policy to transition cuts at or greater than 20 percent.

Response: We have considered the comments and understand the commenters' concerns. We acknowledge some commenters' views that the gradual phase-in of reductions for services that would experience reductions above the threshold (20 percent) is an important principle in determining the best way to implement the phase-in provision. However, we note that the 19 percent reduction maximum also has the advantage of applying the most gradual reduction to services with the greatest reductions (greater than 40 percent). Furthermore, we remain concerned about several practical problems that could arise from utilizing the 50 percent

approach. The first of these problems would occur whenever some codes within the same family of services would meet threshold reductions while others do not. For example if two codes in a four code family would be reduced by an estimated 20 percent while the other two were estimated to be reduced by 19 percent, then the first two would be reduced by 10 percent while the remaining two would be reduced by 19 percent. Such a scenario could easily create rank order anomalies within families of codes. The risks of such anomalies is associated with the financial incentives toward inaccurate downward coding that could not only jeopardize Medicare claims data as an accurate source of information, but more directly could have serious consequences within our ratesetting methodologies for both purposes of budget neutrality and for allocation of PE and MP RVUs. The second practical issue with the 50 percent approach would be that the impact of using the estimated reduction instead of the final reduction to determine whether or not particular codes qualify for the phase-in would be significant. Under the 19 percent approach, values for codes with reductions estimated to be very close to 19 percent would be similar regardless of whether or not we engage in various iterations of budget neutrality adjustments to determine whether or not the phase-in applies. Under the 50 percent approach, determinations that result from repeated iterations of ratesetting calculations and budget neutrality adjustments could decide significant changes in the rates for individual codes (up to 10 percent of the total payment.)

In order to avoid these circumstances and apply the most gradual phase-in possible to codes with the most significant reductions, we continue to believe that a 19 percent reduction as the maximum 1-year reduction is the better approach to determining the phase-in amount.

Comment: One commenter requested that the phase-in period be extended to a greater number of years when entire code groupings are impacted, and when multiple codes are identified within a code grouping and they significantly impact revenue to a specialist or specific provider.

Response: The statute specifies a 2-year phase-in period and does not provide authority to extend the phase-in period as described by the commenter.

After consideration of the comments, we are finalizing the policy to phase in 19 percent of the reduction in value in the first year, and the remainder of the reduction in the second year, as proposed.

4. Applicable Adjustments to RVUs

Section 1848(c)(7) of the Act provides that the applicable adjustments in work, PE, and MP RVUs be phased-in over 2 years for any service for which total RVUs 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 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 professional/technical (PC/TC) component. 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 proposed, therefore, to estimate whether a particular code met 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 professional or technical 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 implementing the phase-in of the RVUs for the component codes billed globally by comparing the global value in the prior year versus the global value in the current year and applying the

phase-in to the global value for the current year and letting the results flow through to the PC and TC for each code, irrespective of their respective changes in value. Similarly, for the codes with site of service differentials, we considered developing an overall, blended set of overall PE RVUs using a weighted average of site of service volume in the Medicare claims data and then comparing that blended value in the prior year versus the blended value in the current year and applying the phase-in to the value for the current year before re-allocating the blended value to the respective PE RVUs in each setting, regardless of the changes in value for nonfacility or facility values. 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 all individual codes in order to effect the appropriate phase-in amount is the most straightforward and fair approach to implementing the 2-year phase-in of significant reductions of total RVUs.

The following is a summary of the comments we received regarding this proposal.

Comment: One commenter requested that CMS confirm that it would apply all adjustments for the phase-in to the PE RVUs only in situations in which just one site of service, or just one component is subject to the phase-in. That is, if both sites of service or both components of a code were subject to the phase-in, then any adjustments would be applied to work and malpractice RVUs as well.

Response: As discussed in the proposal, all adjustments for the phase-in, including for codes with facility and nonfacility RVUs and PC/TC splits, will be applied to the PE RVUs only. We acknowledge that for some codes it would be hypothetically possible to phase in the reductions proportionally across all three RVU components. As we explained in the proposed rule, it would not be practical to do so for services with site of service differentials since each of

the three RVU components represent a different proportion of overall nonfacility or facility RVUs. Therefore, we believe this alternative approach could only work for codes without site of service differentials and those without PC/TC splits, which represents a minority of PFS services. We believe that applying the phase-in for these large categories of codes differently than for the rest of PFS codes would be confusing to the public and make adjustments unpredictable since they would be based on whether or not the service priced in the opposite setting met the phase-in threshold. Furthermore, we remind commenters that because the work RVU is an important allocator of indirect PE in the established methodology, the overall payment impact of any changes in work RVUs is also automatically reflected in corresponding changes to the PE RVUs, whereas changes to direct PE inputs do not have a parallel impact on work RVUs. Therefore, even for individual codes for which it might be possible to establish phase-in values for work RVUs, the necessary adjustments would necessarily be weighted more heavily in PE RVUs.

Comment: With regard to CMS' proposal to consider the RVUs for different sites of service and components independently for the purposes of identifying when and how the phase-in applies, one commenter expressed concerns that the proposed approach ignores the spirit of section 220(e) of the PAMA to benefit physician practices by dampening the year to year impact of large payment reductions. The commenter stated that if CMS adjusts only the PE RVUs, then a large number of codes with greater than 20 percent work RVU reductions could be excluded. The commenter urged CMS to clarify its intent to dampen the effects of year to year reductions to both work RVUs and PE RVUs independently, even for codes with separate facility and non-facility PE RVUs.

Response: We appreciate the commenter's feedback and we acknowledge that our proposed approach would not dampen the year to year reductions in work RVUs. However, our approach would dampen the effect of any payment reductions for all codes, including those

reductions that would result from reductions to work RVUs when such reductions contributed to an overall reduction of 20 percent or greater, consistent with the statutory provision. As a practical matter, we believe that practitioners reporting services furnished to Medicare beneficiaries and paid through the PFS would be paid very similar amounts regardless of which approach we implemented. We also note that the commenter did not provide any information that would help us to understand how the suggested phase-in could be applied to services with site of service differentials.

After consideration of the comments received, we are finalizing this aspect of the phase-in methodology as proposed.

The list of codes subject to the phase-in and the associated RVUs that result from this methodology are available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

G. Changes for Computed Tomography (CT) under the Protecting Access to Medicare Act of 2014 (PAMA)

Section 218(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) amended section 1834 of the Act by establishing a new subsection 1834(p). Effective for services furnished on or after January 1, 2016, new section 1834(p) of the Act reduces payment for the technical component (TC) of applicable CT services paid under the Medicare PFS and applicable CT services paid under the OPPS (a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years). The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes). As specified in section 1834(p)(4) of the Act, the reduction applies for applicable services 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.” Section 1834(p)(4) of the Act also specifies that the Secretary may apply successor standards through rulemaking.

Section 1834(p)(6)(A) of the Act 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 standard set forth in section 1834(p)(4) of the Act (currently the NEMA CT equipment standard) and that such information may be included on a claim and may be a modifier. Section 1834(p)(6)(A) of the Act also provides that such information must 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. Section 218(a)(2) of the PAMA made a conforming amendment to section 1848 (c)(2)(B)(v) of the Act by adding a new subclause (VIII), which provides that, effective for fee schedules established

beginning with 2016, reduced expenditures attributable to the application of the quality incentives for computed tomography under section 1834(p) of the Act shall not be taken into account for purposes of the budget neutrality calculation under the PFS.

To implement this provision, in the CY 2016 PFS proposed rule (80 FR 41716), we proposed to establish a new modifier to be used on claims that describes CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR-29-2013. We proposed that, beginning January 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the CPT codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scans. We stated that the use of this proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act. We received the following comments on our proposal to require the modifier to be used on claims:

Many commenters endorsed the use of quality incentives to improve patient safety and optimize the use of radiation when providing CT diagnostic imaging services. Several commenters were supportive of the proposal to establish the modifier to identify CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR-29-2013.

Comment: Several commenters requested that we delay implementation of section 1834(p) of the Act so that they have additional time to comply before the payment reduction becomes effective.

Response: The statute requires that we apply the payment adjustment for computed tomography services furnished on or after January 1, 2016. Given this language, we believe that we must implement this provision beginning January 1, 2016. Therefore, we are not delaying implementation of this provision. We note that the payment reduction for 2016 is 5 percent, and it then increases to 15 percent in subsequent years. Hospitals and suppliers that furnish services

that do not meet the equipment standard as of January 1, 2016, will receive this 5 percent payment reduction during 2016, but will have an opportunity to upgrade their CT scanners before the larger payment adjustment that takes effect beginning in CY 2017.

Comment: One commenter cited section 1834 (p)(4) of the Act, which specifies that through rulemaking, the Secretary may apply successor standards for CT equipment. The commenter indicated that CMS should develop successor standards that exempt CT scans performed on cone beam CT (CBCT) scanners that are FDA cleared only for imaging of the head from the requirement for Automatic Exposure Control (AEC) capability. This request was based on the AEC capability being unavailable on CBCT scanners.

Response: Although we agree with the commenter that the Secretary has authority to apply successor standards for CT equipment through notice and comment rulemaking, we would like to gain some experience with the NEMA Standard XR-29-2013 before adopting a successor standard. Therefore, we are not adopting a successor standard to the NEMA Standard XR-29-2013 in this final rule with comment period, but may consider doing so in future rulemaking.

After consideration of the public comments we received, we are finalizing the establishment of new modifier, “CT.” This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2016, with the label “CT,” and the long descriptor “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 January 1, 2016, hospitals and suppliers will be required to report the modifier “CT” on claims for CT scans described by any of the CPT codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR-29-2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

H. 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.B.5. of this final rule with comment period. 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 proposed new values in the CY 2016 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 the CY 2016 proposed rule, we are establishing interim final values in this final rule with comment period, consistent with previous practice. In this final rule with comment period, we considered all comments received in response to proposed values for codes in our proposed rule, including alternative recommendations to those used in developing the proposed rule.

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 are establishing final values for those codes in this final rule with comment period. However, the RUC recommendations included CPT tracking codes instead of the actual 2016 CPT codes, which were first made available to the public subsequent to the publication of the CY 2016 proposed rule with comment period. 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 developed and used alternative 5-character placeholder codes for use in the proposed rule.

The final CPT codes are included and used for purposes of discussion in this final rule with comment period. Table 9 lists the CPT tracking codes, the CMS placeholder codes, and the final CPT codes for all new CPT codes included in the CY 2016 PFS proposed rule.

TABLE 9: 2016 Final Rule HCPCS Placeholder to CPT Code Numbers

CPT Tracking Code	CMS Placeholder Code	CPT 2016	Short Descriptor
3160X1	3160A	31652	Bronch ebus samplng 1/2 node
3160X2	3160B	31653	Bronch ebus samplng 3/> node
3160X3	3160C	31654	Bronch ebus ivntj perph les
3347X1	3347A	33477	Implant tcat pulm vlv perq
3725X1	3725A	37252	Intrvasc us noncoronary 1 st
3725X2	3725B	37253	Intrvasc us noncoronary addl
3940X1	3940A	39401	Mediastinoscopy w/medstnl bx
3940X2	3940B	39402	Mediastinoscopy w/lmph nod bx
5039X1	5039A	50430	Njx px nfrosgrm &/urtrgrm
5039X2	5039B	50431	Njx px nfrosgrm &/urtrgrm
5039X3	5039C	50432	Plmt nephrostomy catheter
5039X4	5039D	50433	Plmt nephroureteral catheter
5039X13	5039M	50434	Convert nephrostomy catheter
5039X5	5039E	50435	Exchange nephrostomy cath
5069X7	5069G	50693	Plmt ureteral stent prq
5069X8	5069H	50694	Plmt ureteral stent prq
5069X9	5069I	50695	Plmt ureteral stent prq
5443X1	5443A	54437	Repair corporeal tear
5443X2	5443B	54438	Replantation of penis
657XX7	657XG	65785	Impltj ntrstrml crnl rng seg
692XXX	692XX	69209	Remove impacted ear wax uni
7208X1	7208A	72081	X-ray exam entire spi 1 vw
7208X2	7208B	72082	X-ray exam entire spi 2/3 vw
7208X3	7208C	72083	X-ray exam entire spi 4/5 vw
7208X4	7208D	72084	X-ray exam entire spi 6/> vw
7778X1	7778A	77767	Hdr rdnc1 skn surf brachytx
7778X2	7778B	77768	Hdr rdnc1 skn surf brachytx
7778X3	7778C	77770	Hdr rdnc1 ntrstl/icav brchtx
7778X4	7778D	77771	Hdr rdnc1 ntrstl/icav brchtx
7778X5	7778E	77772	Hdr rdnc1 ntrstl/icav brchtx
8835X0	8835X	88350	Immunofluor antib addl stain
9254X1	9254A	92537	Caloric vstblr test w/rec

CPT Tracking Code	CMS Placeholder Code	CPT 2016	Short Descriptor
9254X2	9254B	92538	Caloric vstblr test w/rec
99176X	9917X	99177	Ocular instrumnt screen bil
9935XX1	9935A	99415	Prolong clincl staff svc
9935XX2	9935B	99416	Prolong clincl staff svc add
GXXX1	GXXX1	G0296	Visit to determ ldct elig
GXXX2	GXXX2	G0297	Ldct for lung ca screen

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 RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review of recommended work RVUs and time 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 work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, CMS has frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. Since the statute specifically defines the work component as the resources in time and intensity required in furnishing the service and the published literature on valuing work has recognized the key role of time in overall work, we have also refined the work RVUs for particular codes in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intra-service time.

Comment: Several commenters objected to CMS' use of these methodologies as unprecedented and invalid in the context of the development of PFS RVUs.

Response: We appreciate that many commenters, including the RUC, have maintained that magnitude estimation, informed by survey results, is the only appropriate method for valuation of PFS services. However, we have observed that the approaches used by the RUC in developing recommended work RVUs have resulted in recommended values that do not adequately address significant changes in assumptions regarding the amount of time required to furnish particular PFS services. Since section 1848(c)(1)(A) of the Act explicitly identifies time as one of the two kinds of resources that comprise the work component of PFS payment, we do not believe that our use of the above methodologies is inconsistent with the statutory requirements related to the maintenance of work RVUs, and we have regularly used these and other methodologies in developing values for PFS services. 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. In our review of RUC-recommended values, we have noted that the RUC also uses a variety of methodologies to develop work RVUs for individual services, and subsequently validates the results of these approaches through magnitude estimation. We believe that our discrete use of methodologies that compare the time resources among PFS codes is fundamentally similar to that approach, but better facilitates our ability to identify the most accurate work RVU for individual services by explicitly considering the significance of time in the estimate of total work.

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

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. 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 multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes \times 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

Table 13 contains a list of codes for which we proposed work RVUs; this includes all RUC recommendations received by February 10, 2015. When the proposed work RVUs varied from those recommended by the RUC or for which we do not have RUC recommendations, we address those codes in the portions of this section that are dedicated to particular codes. The work RVUs and other payment information for all CY 2016 payable codes are available in Addendum B. Addendum B is available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/downloads/>. The time values for all CY 2016 codes are listed in a file called “CY 2016 PFS Work Time,” available on the CMS website under downloads for the CY 2016 PFS final rule with comment period 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 inputs includes many refinements that are common across codes as well as refinements that are specific to particular services. Table 16 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this final rule with comment period, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is \$0.32 or less, the refinement has no impact on the interim 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 14 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 final direct PE inputs for CY 2016 are displayed in the final CY 2016 direct PE input database, available on the CMS website under the downloads for the CY 2016 final 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 final 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 interim final direct PE inputs. In other cases, CMS refinement of RUC-recommended work times prompts necessary adjustments in the direct PE inputs.

We proposed to remove the 6 minutes of clinical labor time allotted to “discharge management, same day (0.5 x 99238)” in the facility setting from a number of procedures under review. We proposed to align the clinical labor for discharge day management to align the work time assigned in the work time file. We made these proposed refinements under the belief that we should not allocate clinical labor staff time for discharge day management if there is no discharge visit included in the procedure’s global period.

Comment: Several commenters, including the RUC, disagreed with CMS and suggested that the clinical staff time in the facility setting may not conform with work time for discharge

day management in a given code. Commenters stated that the work discharge time reflects the work involved in discharging from a facility setting. Therefore, if the service is typically performed in the nonfacility setting, the post-service time for a CPT code 99238 discharge visit would not be included. However, since the inputs for PE are differentiated by site of service, the time for discharge day might be included in the facility inputs, even if the service is infrequently provided in the facility setting overall. Although the commenters agreed that there should not be clinical staff time for discharge management assigned to 0-day global procedures, the commenters requested that this clinical staff time be restored for the nine 10-day global procedures under review. Commenters stressed that clinical staff must instruct the patient regarding home care prior to the post-operative visit and call in any necessary prescriptions. Commenters also requested that this clinical labor time be included as two, 3-minute phone calls under the task “Conduct phone calls/call in prescriptions.”

Response: We understand and agree that when cases typically performed in the non-facility setting are performed in the facility setting, discharge day management may not be typical for the code overall even if discharge day management activities may be typical when the service is furnished in the facility setting. However, we also believe that if a patient’s conditions are serious enough to warrant treatment in the facility setting, then it is likely that the patient will also be receiving additional services that already include the resource costs involved with clinical labor tasks associated with discharge day management. Therefore, we do not believe that it is appropriate to include the additional time for staff phone calls for these services generally furnished in the office setting.

We have thus far been addressing the subject of discharge day management on a code-by-code basis. Based on the comments received, we believe there is a need for a broader policy concerning the proper treatment of this issue. We will consider this subject for future rulemaking.

After consideration of the comments received, we are finalizing our current refinements to discharge day management clinical labor time.

(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 the 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 and have reiterated these objections in comments regarding the proposed direct PE inputs. We are responding to these comments by referring the commenters to our extensive discussion in response to the same 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 conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the 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, we review these tasks to determine whether they are fully distinct from existing clinical labor tasks, typically included for other clinically similar services under the PFS, and thoroughly explained in the recommendation. For those tasks that do not meet these criteria, we do not accept these newly recommended clinical labor tasks; 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 16 in section II.A.3. of this final rule with comment period for a discussion of these standards.

Comment: Several commenters stated that our standard clinical labor inputs for digital imaging inputs for many different codes do not reflect the accurate number of minutes associated with clinical labor tasks for individual services.

Response: In the CY 2015 PFS final rule with comment period (79 FR 67561), we finalized the transition from film-based to digital direct PE inputs for imaging services. In the CY 2016 PFS proposed rule, we sought comment on the appropriate values for the clinical labor tasks associated with digital imaging. Please see section II.B. of this rule for a discussion of those policies. We believe that adherence to these standards produces the most accurate estimate of the resource costs for these kinds of tasks and supports relativity within the development of PE RVUs. For these reasons, absent extenuating factors for specific codes, we are finalizing

interim final direct PE inputs that adhere to these standards.

(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

Over several rulemaking cycles, we have proposed and finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure (76 FR 73043 through 73049). Our CY 2016 proposed direct PE inputs conform to these policies. This includes not incorporating the recommended power table (EF031) where it was included during the intraservice period, since a stretcher is the standard item in the moderate sedation package. These refinements are reflected in the final CY 2016 PFS direct PE input database and detailed in Table 16.

Comment: One commenter agreed with CMS’ proposal to include the use of a stretcher in the standard moderate sedation package, and that the time allocated for the stretcher should be the entire post procedure recovery period. The commenter recommended that CMS work with the RUC and specialty groups before removing the power table input from the service period of any codes.

Response: We appreciate the commenter’s support for the standard moderate sedation package, but we do not believe we should consult with the RUC prior to implementing the standards in developing or finalizing direct PE inputs. However, will consider the appropriate direct PE inputs for each code under review.

(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 that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2016, we received invoices for several new supply and equipment items. We have accepted the majority of these items and added them to the direct PE input database. Tables 18 and 19 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this final rule with comment period, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database. 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 18 and 19 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 use the price listed on the invoice that accompanies the

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

The following is a summary of the comments we received regarding new supply and equipment items.

Comment: Several commenters stated that they had concerns regarding the process of pricing new supply and equipment items for the PFS. The current process requires the submission of recently paid invoices for CMS to consider pricing a new direct PE item. The commenters asked CMS to develop a new pathway to submit pricing information that will protect physicians and vendors, since publishing copies of paid invoices, even when redacted, does not sufficiently protect private identities.

Response: We share commenters' concerns about protecting the privacy of practitioners and vendors during invoice submission. We welcome and will consider additional feedback and suggestions submitted by stakeholders regarding alternate avenues to provide updated pricing information for individual supplies and equipment.

Comment: A commenter stated that although the commenter understands that CMS cannot accurately value the typical cost of a supply or equipment if the agency is not provided with sufficient pricing information, they disagreed with CMS' decision to list the item in question in the direct PE database without assigning any value to it, as this can significantly affect the overall PE value for that service. The commenter requested that CMS highlight those cases where the price of a supply or equipment item is not being finalized due to inadequate documentation, so that there is an opportunity to provide additional resources that might assist in assigning an accurate value.

Response: We agree with the commenter that a lack of sufficient pricing information can often be problematic in assigning an accurate value to new supplies and equipment. Although we do not specifically identify all such items in the preamble to PFS rules, we note that stakeholders can easily identify items without prices in the direct PE input database files that are included as downloads with each PFS rule. We urge the public to submit a comment alerting us to items without a price that appear to be errors in the database. As detailed above, we also encourage the submission of invoices to help provide up-to-date, accurate pricing information for medical supplies and equipment.

Comment: A commenter wrote to express concern with the pricing of three supplies: probe, radiofrequency, three array (StarBurstSDE) (SD109) from \$1995 to \$353.44; gas, helium (SD079) from 25 cents per cubic foot to one cent per cubic foot; and gas, argon (SD227) from 25 cents per cubic foot to less than one cent per cubic foot. The commenter added that there was no evidence that supported lower prices for these supplies, and urged CMS to retain the existing pricing for these supply items. The commenter stated that CMS' concerns regarding the price of these supplies were not addressed in the proposed rule, which did not allow opportunity for public comment.

Response: The prices of these three supplies were updated in response to invoices

received during the previous calendar year. We appreciate the commenters' feedback and we recognize that it would have been easier for stakeholders to identify the prices had they been included on the Invoices Received for Existing Direct PE Inputs table in the proposed rule. We believe that the commenter may have been mistaken about the pricing of supplies SD079 and SD227. Both of these supplies have increased in price, from 25 cents per cubic foot to 57 cents and 32 cents per cubic foot, respectively. Neither supply has been lowered in price to one cent per cubic foot. Absent better data sources, we continue to believe that the supply prices listed in the public use files for the CY 2016 PFS proposed rule are the most accurate values for these items.

Comment: Many commenters wrote to express their concern over the pricing of the radiofrequency generator (NEURO) (EQ214) equipment affecting CPT codes 41530, 43228, 43229, 43270, 64633, 64634, 64635 and 64636. Commenters indicated that the invoice for this new equipment item was submitted in relation to CPT code 41530, and the equipment is not the same radiofrequency generator used to perform the services described by CPT codes 64633, 64634, 64635 and 64636. Commenters requested that the equipment input represented in the invoice be assigned an equipment code separate from existing code EQ214 and that CMS maintain the current price of \$32,900 for EQ214.

Response: We appreciate the additional information provided by commenters regarding the pricing of the radiofrequency generator equipment. After consideration of comments received, we will create a new equipment code for the radiofrequency generator described in the submitted invoice, and assign this equipment to CPT codes 41530, 43228, 43229, and 43270. For CPT codes 64633, 64634, 64635, and 64636, we will maintain the current price of \$32,900 for EQ214 and maintain this equipment.

Comment: One commenter submitted additional invoices regarding the pricing of the PrePen (SH103) supply. The commenter requested that CMS update the price of the PrePen to

\$92 based on an average of the four invoices submitted.

Response: We appreciate the commenter's submission of additional pricing information regarding the PrePen supply. We note that three of the four submitted invoices reported a price of \$86 for supply item "PrePen" (SH103); we believe that this represents the typical price of this supply.

Therefore, after consideration of the comments received, we are increasing the price of supply SH103 from \$83 to \$86.

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

Several of the PE worksheets included in RUC recommendations contained clinical labor minutes assigned to the service period in the facility setting. Our proposed inputs did 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. We received no general comments that addressed this issue; we will address code-specific refinements to clinical labor in the individual code sections.

(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 by the RUC, we did not propose to include the time for this equipment item from these services. In the proposed rule, we solicited comments on whether there is a rationale for including this additional light source as a direct PE input for these procedures.

The following is a summary of the comments we received.

Comment: One commenter stated that if CMS believes two light sources are duplicative for these procedures, the commenter recommended retaining input EQ167 and removing input

EQ170 (the fiberoptic headlight), as the xenon light source is compatible with various items and can serve as the light source throughout the procedures.

Response: We appreciate the additional information from the commenter regarding the appropriate use of these two light sources.

After consideration of comments received, we are restoring input EQ167 and removing input EQ170 with the same number of equipment minutes for CPT codes 30300, 31295, 31296, 31297, and 92511.

(9) Identification of Database Errors

Several commenters identified possible errors in the direct PE database that did not apply to CPT codes under review. The following is a summary of the comments we received regarding potential database entry errors.

Comment: A commenter located a potential error for CPT code 33262 (Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system) where the PE RVU dropped from 3.68 in 2015 to 2.35 in the CY 2016 PFS proposed rule. The commenter pointed out that no changes were made to the direct PE inputs for the code, and similar codes within the same family retained the same PE value. The commenter recommended that CMS review this PE RVU and make a correction in the final rule.

Response: For CPT code 33262, the pre-existing direct PE inputs for this code were inadvertently not included in the development of the CY 2016 PFS proposed direct PE input database. We believe this was the result of a data error, and therefore, we are restoring the direct PE inputs to this service.

Comment: One commenter indicated that the underlying line item direct inputs for a series of CPT codes were missing from the individual labor, equipment, and supply public use files. The commenter provided a list of the ten codes affected by this issue, and asked whether this was the result of a technical error.

Response: The ten codes in question were all procedures that the CPT Editorial Panel has assigned for deletion in CY 2016. These codes appeared in error in our public use files for the CY 2016 PFS proposed rule. We have identified the technical issue that was causing this error and corrected it in the CY 2016 final direct PE input database.

Comment: One commenter identified a group of codes where the calculated clinical labor costs (based on the underlying direct input labor file) differed from the CMS summary labor findings. The commenter asked if there were instances where CMS was applying different labor inputs from those published in the files released with the rule.

Response: We appreciate the commenter bringing this issue regarding conflicting information in the CY 2016 PFS proposed rule public use files to our attention. This discrepancy was caused by an error in the creation of the public use files that undercounted the number of clinical labor minutes assigned to the postoperative E/M visits assigned to codes with 10-day and 90-day global periods. This error did not affect the proposed rates in the proposed rule, only the displayed values in the “labor task detail” public use file. We have corrected this issue in the public use files for the CY 2016 final direct PE input database.

Comment: A commenter indicated that for several codes, the CMS file for work times did not appear to be updated with the RUC-approved times. In particular, the pre-evaluation time and immediate post-service time appeared to be missing from the CMS file.

Response: These incorrect work times have been corrected in the CY 2016 final direct PE input database.

(10) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPFS Cap

We note that services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services and therapy services, and the list of procedures that meet the definition of imaging under section 5102(b) of the DRA and are

therefore subject to the OPSS cap for the upcoming calendar year are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2016 are available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html>.

5. Methodology for Establishing Malpractice RVUs

As discussed in section II.B. of this final rule with comment period, our malpractice methodology uses a crosswalk to establish risk factors for new services until utilization data becomes available. Table 10 lists the CY 2016 HCPCS codes and their respective source codes used to set the CY 2016 MP RVUs. The MP RVUs for these services are reflected in Addendum B on the CMS Web site at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>.

TABLE 10: CY 2016 Malpractice Crosswalk

CY 2016 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
10035	Perq Dev Soft Tiss 1St Imag	19285	Perq dev breast 1st us imag
10036	Perq Dev Soft Tiss Add Imag	19286	Perq dev breast add us imag
26356	Repair finger/hand tendon	26356	Repair finger/hand tendon
26357	Repair finger/hand tendon	26357	Repair finger/hand tendon
26358	Repair/graft hand tendon	26358	Repair/graft hand tendon
41530	Tongue base vol reduction	41530	Tongue base vol reduction
43210	Egd esophagogastrc fndoplsty	43276	Ercp stent exchange w/dilate
47531	Injection For Cholangiogram	49450	Replace g/c tube perc
47540	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
47541	Plmt Access Bil Tree Sm Bwl	47500	Injection for liver x-rays
47542	Dilate Biliary Duct/Ampulla	47550	Bile duct endoscopy add-on
47543	Endoluminal Bx Biliary Tree	47550	Bile duct endoscopy add-on
47544	Removal Duct Gblldr Calculi	47630	Remove bile duct stone
47532	Injection For Cholangiogram	49407	Image cath fluid trns/vgnl
47533	Plmt Biliary Drainage Cath	47510	Insert catheter bile duct
47534	Plmt Biliary Drainage Cath	47511	Insert bile duct drain
47535	Conversion Ext Bil Drg Cath	47505	Injection for liver x-rays

CY 2016 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
47536	Exchange Biliary Drg Cath	49452	Replace g-j tube perc
47537	Removal Biliary Drg Cath	47505	Injection for liver x-rays
47538	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
47539	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
49185	Sclerotx Fluid Collection	49407	Image cath fluid trns/vgnl
50606	Endoluminal Bx Urtr Rnl Plvs	50955	Ureter endoscopy & biopsy
50705	Ureteral Embolization/Occl	50393	Insert ureteral tube
50706	Balloon Dilate Urtrl Strix	50395	Create passage to kidney
55866	Laparo radical prostatectomy	55866	Laparo radical prostatectomy
61645	Perq Art M-Thrombect &/Nfs	37218	Stent placemt ante carotid
61650	Evasc Prlng Admn Rx Agnt 1St	37202	Transcatheter therapy infuse
61651	Evasc Prlng Admn Rx Agnt Add	37202	Transcatheter therapy infuse
64461	Pvb Thoracic Single Inj Site	64490	Inj paravert f jnt c/t 1 lev
64462	Pvb Thoracic 2Nd+ Inj Site	64480	Inj foramen epidural add-on
64463	Pvb Thoracic Cont Infusion	64446	N blk inj sciatic cont inf
64553	Implant neuroelectrodes	64553	Implant neuroelectrodes
64555	Implant neuroelectrodes	64555	Implant neuroelectrodes
64566	Neuroeltrd stim post tibial	64566	Neuroeltrd stim post tibial
65778	Cover eye w/membrane	65778	Cover eye w/membrane
65779	Cover eye w/membrane suture	65779	Cover eye w/membrane suture
65780	Ocular reconst transplant	65780	Ocular reconst transplant
65855	Trabeculoplasty Laser Surg	65855	Laser surgery of eye
66170	Glaucoma surgery	66170	Glaucoma surgery
66172	Incision of eye	66172	Incision of eye
67107	Repair Detached Retina	67107	Repair detached retina
67108	Repair Detached Retina	67108	Repair detached retina
67110	Repair detached retina	67110	Repair detached retina
67113	Repair Retinal Detach Cplx	67113	Repair retinal detach cplx
67227	Dstrj Extensive Retinopathy	67227	Treatment of retinal lesion
67228	Treatment X10Sv Retinopathy	67228	Treatment of retinal lesion
72170	X-ray exam of pelvis	72170	X-ray exam of pelvis
73501	X-Ray Exam Hip Uni 1 View	72170	X-ray exam of pelvis
73502	X-Ray Exam Hip Uni 2-3 Views	72170	X-ray exam of pelvis
73503	X-Ray Exam Hip Uni 4/> Views	72170	X-ray exam of pelvis
73521	X-Ray Exam Hips Bi 2 Views	72170	X-ray exam of pelvis
73522	X-Ray Exam Hips Bi 3-4 Views	72170	X-ray exam of pelvis
73523	X-Ray Exam Hips Bi 5/> Views	72170	X-ray exam of pelvis
73551	X-Ray Exam Of Femur 1	72170	X-ray exam of pelvis
73552	X-Ray Exam Of Femur 2/>	72170	X-ray exam of pelvis

CY 2016 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
74712	Mri Fetal Sngl/1St Gestation	72195	Mri pelvis w/o dye
74713	Mri Fetal Ea Addl Gestation	72195	Mri pelvis w/o dye
77778	Apply Interstit Radiat Compl	77778	Apply interstit radiat compl
77790	Radiation handling	77790	Radiation handling
78264	Gastric Emptying Imag Study	78264	Gastric emptying study
78265	Gastric Emptying Imag Study	78264	Gastric emptying study
78266	Gastric Emptying Imag Study	78264	Gastric emptying study
91200	Liver elastography	91133	Electrogastrography w/test
93050	Art pressure waveform analys	93784	Ambulatory bp monitoring
95971	Analyze neurostim simple	95971	Analyze neurostim simple
95972	Analyze Neurostim Complex	95972	Analyze neurostim complex

6. CY 2016 Valuation of Specific Codes

TABLE 11: CY 2016 Work RVUs for New, Revised and Potentially Misvalued Codes with Proposed Values in the CY 2016 PFS Proposed Rule

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
11750	Excision of nail and nail matrix, partial or complete (eg, ingrown or deformed nail), for permanent removal;	2.50	1.58	1.58
20240	Biopsy, bone, open; superficial (eg, ilium, sternum, spinous process, ribs, trochanter of femur)	3.28	2.61	2.61
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	14.64	20.00	20.00
31652	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	4.71	4.71
31653	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	5.21	5.21
31654	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	1.40	1.40

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)	2.78	2.78	2.78
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites	3.36	3.36	3.36
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple	4.16	4.16	4.16
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe	3.80	3.80	3.80
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)	4.09	4.00	4.00
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (List separately in addition to code for primary procedure)	1.03	1.03	1.03
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (List separately in addition to code for primary procedure)	1.32	1.32	1.32
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	NEW	25.00	25.00
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection	19.68	18.00	18.00
37252	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	1.80	1.80
37253	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
38570	Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple	9.34	8.49	8.49
38571	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy	14.76	12.00	12.00
38572	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy and peri-aortic lymph node sampling (biopsy), single or multiple	16.94	15.60	15.60
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	NEW	5.44	5.44
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	NEW	7.25	7.25

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)	C	20.38	20.38
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.05	0.90	0.97
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	I	1.48	1.48
44382	Ileoscopy, through stoma; with biopsy, single or multiple	1.27	1.20	1.27
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	I	2.88	2.95
44385	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or JJ]); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.82	1.23	1.30
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or JJ]); with biopsy, single or multiple	2.12	1.53	1.60
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	2.82	2.75	2.82
44389	Colonoscopy through stoma; with biopsy, single or multiple	3.13	3.05	3.12
44390	Colonoscopy through stoma; with removal of foreign body(s)	3.82	3.77	3.84
44391	Colonoscopy through stoma; with control of bleeding, any method	4.31	4.22	4.22
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	3.81	3.63	3.63
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	4.42	4.13	4.13
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	I	4.44	4.44
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed)	I	4.73	4.80
44403	Colonoscopy through stoma; with endoscopic mucosal resection	I	5.53	5.60
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance	I	3.05	3.12
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	I	3.33	3.33
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures	I	4.13	4.20
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 adjacent structures	I	5.06	5.06

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	I	4.24	4.24
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	0.96	0.77	0.84
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	1.15	1.07	1.14
45332	Sigmoidoscopy, flexible; with removal of foreign body(s)	1.79	1.79	1.86
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	1.79	1.65	1.65
45334	Sigmoidoscopy, flexible; with control of bleeding, any method	2.73	2.10	2.10
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance	1.46	1.07	1.14
45337	Sigmoidoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	2.36	2.20	2.20
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	2.34	2.15	2.15
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation	1.89	1.35	1.35
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination	2.60	2.15	2.22
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s)	4.05	3.08	3.08
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)	I	2.84	2.91
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	I	2.75	2.82
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	I	3.55	3.62
45350	Sigmoidoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	I	1.78	1.78
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	3.69	3.29	3.36
45379	Colonoscopy, flexible; with removal of foreign body(s)	4.68	4.31	4.38
45380	Colonoscopy, flexible; with biopsy, single or multiple	4.43	3.59	3.66
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	4.19	3.59	3.66
45382	Colonoscopy, flexible; with control of bleeding, any method	5.68	4.76	4.76
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	4.69	4.17	4.17
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	5.30	4.67	4.67
45386	Colonoscopy, flexible; with transendoscopic balloon dilation	4.57	3.87	3.87

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
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)	I	4.98	4.98
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed)	I	5.27	5.34
45390	Colonoscopy, flexible; with endoscopic mucosal resection	I	6.07	6.14
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures	5.09	4.67	4.74
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 adjacent structures	6.54	5.60	5.60
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	I	4.78	4.78
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	I	4.30	4.30
46500	Injection of sclerosing solution, hemorrhoids	1.69	1.42	1.42
46601	Anoscopy; diagnostic, with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed	I	1.60	1.60
46607	Anoscopy; with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple	I	2.20	2.20
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	83.64	90.00	90.00
50430	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
50431	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	1.10	1.10
50432	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	4.25	4.25
50433	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	5.30	5.30

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
50435	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	1.82	1.82
50434	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	4.00	4.00
50693	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	4.21	4.21
50694	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 separ	NEW	5.50	5.50
50695	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	7.05	7.05
54437	Repair of traumatic corporeal tear(s)	NEW	11.50	11.50
54438	Replantation, penis, complete amputation including urethral repair	NEW	22.10	24.50
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical	17.95	17.95	17.95
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic	17.25	17.25	17.25
65785	Implantation of intrastromal corneal ring segments	NEW	5.39	5.39
68801	Dilation of lacrimal punctum, with or without irrigation	1.00	0.82	0.82
68810	Probing of nasolacrimal duct, with or without irrigation;	2.15	1.54	1.54
68811	Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia	2.45	1.74	1.74
68815	Probing of nasolacrimal duct, with or without irrigation; with insertion of tube or stent	3.30	2.70	2.70
68816	Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation	3.06	2.10	2.10
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.22	0.22
72081	Entire spine x ray, one view	NEW	0.26	0.26

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
72082	Entire spine x-ray; 2 or 3 views	NEW	0.31	0.31
72083	Entire spine x-ray; 4 or 5 views	NEW	0.35	0.35
72084	Entire spine x-ray; min 6 views	NEW	0.41	0.41
73060	Radiologic examination; humerus, minimum of 2 views	0.17	0.16	0.16
73560	Radiologic examination, knee; 1 or 2 views	0.17	0.16	0.16
73562	Radiologic examination, knee; 3 views	0.18	0.18	0.18
73564	Radiologic examination, knee; complete, 4 or more views	0.22	0.22	0.22
73565	Radiologic examination, knee; both knees, standing, anteroposterior	0.17	0.16	0.16
73590	Radiologic examination; tibia and fibula, 2 views	0.17	0.16	0.16
73600	Radiologic examination, ankle; 2 views	0.16	0.16	0.16
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)	C	C	C
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple	I	0.00	I
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex	I	0.00	I
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed	I	0.58	I
77402	Radiation treatment delivery, >= 1 MeV; simple	I	0.00	I
77407	Radiation treatment delivery, >= 1 MeV; intermediate	I	0.00	I
77412	Radiation treatment delivery, >= 1 MeV; complex	I	0.00	I
77767	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel	NEW	1.05	1.05
77768	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	1.40	1.40
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel	NEW	1.95	1.95
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels	NEW	3.80	3.80
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels	NEW	5.40	5.40
88346	Immunofluorescent study, each antibody; direct method	0.86	0.74	0.74
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	NEW	0.56	0.56
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure	0.73	0.73	0.73

HCPCS Code	Long Descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure	0.88	0.88	0.88
91299	Unlisted diagnostic gastroenterology procedure	C	C	C
92537	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations)	NEW	0.60	0.60
92538	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations)	NEW	0.30	0.30
99174	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral	N	N	N
99177	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with on-site analysis	NEW	N	N
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate	I	1.50	1.50
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List separately in addition to code for primary procedure)	I	1.40	1.40
G0104	Colorectal cancer screening; flexible sigmoidoscopy	0.96	0.77	0.84
G0105	Colorectal cancer screening; colonoscopy on individual at high risk	3.69	3.29	3.36
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk	3.69	3.29	3.36

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. In the CY 2016 PFS proposed rule, we made use of similar methodologies in establishing the proposed 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 12 reflects how we applied this methodology and the values we proposed. 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 code 43235 of 2.19 to arrive at our proposed work RVU for the base colonoscopy CPT code 45378 of 3.29. We used this value as the base code in the incremental methodology for establishing the proposed work RVU for the other base codes in the colonoscopy subfamilies which were then used to value the other codes in that subfamily.

Comment: Many commenters expressed concerns that the proposed values for the lower GI code set will hinder efforts to reduce the incidence of colorectal cancer through detection and treatment by limiting access to screenings. Comments stated, “According to a poll of more than 550 gastroenterologists, more than half of the respondents plan to limit new Medicare patients if the proposed cuts are implemented; 55 percent plan to limit procedures to Medicare patients; and 15 percent are considering opting out of Medicare entirely. These findings suggest that GI physicians may not be able to maintain the current mix of Medicare patients and protect the financial viability of their practices.” Some commenters specifically disagreed with CMS’ methodology of applying an incremental difference between the base procedure for upper GI and lower GI, stating they believe that is a misapplication of the incremental approach and some noted that they believe that the upper and lower GI services are clinically distinct. Additionally, many commenters expressed disappointment that CMS did not consider the survey results, which they believe are the most reliable indicator of the work involved in colonoscopy. These commenters suggested that CMS adopt the RUC-recommended values for the lower GI code set.

Additionally, the affected specialty societies suggested that we accept their original recommendations (a work RVU of 3.51 for the base colonoscopy code, CPT code 45378). Some commenters stated that new colorectal cancer screening protocols have resulted in increased work due to the attention required to identify and remove precancerous lesions.

Response: In developing the proposed work RVUs, we did consider the survey data. However, we considered the survey data in the context of the work RVUs for services within the broader endoscopy family. While we continue to believe that relativity among families of codes is important and view the upper and lower endoscopy codes as one code family, in the context of receiving many comments urging us to accept the RUC-recommended value for diagnostic colonoscopy (and thus the screening colonoscopy), we reconsidered the differences between the RUC-recommended value and our proposed RVUs. We do not believe the relatively small difference between these two values is itself likely to present significant issues in PFS relativity. Therefore, we agree with commenters that the RUC-recommended values generally reflect the work resources involved in furnishing the service and we are finalizing the RUC-recommended value of 3.36 RVUs for the base colonoscopy code, CPT code 45378, and are adjusting the valuation of all the other codes in the lower GI code set using that base with the incremental difference methodology. We also note that while we appreciate and share commenters' interest in maintaining beneficiaries' access to screening colonoscopies where appropriate under the current benefit, we believe that establishing RVUs that most accurately reflect the relative resource costs involved in furnishing services paid under the PFS is not only required by the statute, but also important to preserve and promote beneficiary access to all PFS services.

Comment: A few commenters requested that CMS delay finalizing values for the lower GI codes until codes that are used to report moderate sedation are separately valued, since implementation of those codes will require a methodology for removing the work RVUs for moderate sedation from the endoscopy codes.

Response: We will review and consider recommendations from the medical community about the work RVUs associated with moderate sedation and will address the valuation of moderate sedation separately. Since moderate sedation is a broad, cross-cutting issue that affects many specialties and code families, we do not believe that it is appropriate to delay finalizing values for all codes with moderate sedation, and therefore, will not do so for the GI codes.

Comment: A few commenters stated disagreement with CMS' proposed PE refinement to remove the mobile instrument table (EF027) from codes 45330 and 45331 on the basis that the procedures do not include moderate sedation. The commenter noted that, "while the mobile instrument table is part of the moderate sedation standard package and moderate sedation is not inherent in the procedure, it is still a necessary part of flexible sigmoidoscopy codes 45330 and 45331."

Response: We agree with the commenter that the mobile instrument table is typically involved in furnishing these services, even though moderate sedation may not be inherent in the procedure. Therefore, we have included the mobile instrument table (EF027) in the direct PE input database for codes 45330 and 45331.

Comment: We received a comment on the proposed PE refinements made to CPT code 45330, stating that the RUC approved sterile water for CPT code 43450 instead of distilled water due to the risk of infections and potential for contamination. The commenter stated an expectation that all GI endoscopy codes that currently contain distilled water should be revised to include sterile water instead.

Response: We have considered the comment; however, we re-examined the RUC-recommended direct PE inputs, and we did not identify the sterile water as part of that recommendation. Additionally, the commenter did not provide a detailed rationale for the use of sterile water over distilled water. Therefore, for CY 2016, we are finalizing the inputs for code

45330 as proposed. However, we are seeking additional information regarding these inputs (including rationale and explanation for the use of the commenter’s recommended inputs) and we will consider this issue for future rulemaking.

TABLE 12: Application of the Incremental Difference Methodology

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base Procedure	Base RVU	Increment	Increment Value	Proposed WRVU	Finalized WRVU (Using 3.36 RVUs for the base)
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	0.97
44382	Ileoscopy, through stoma; with biopsy, single or multiple	1.27	1.27	Ileoscopy	0.9	Biopsy	0.3	1.2	1.27
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	2.95
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	1.3

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base Procedure	Base RVU	Increment	Increment Value	Proposed WRVU	Finalized WRVU (Using 3.36 RVUs for the base)
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	1.6
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	2.82
44389	Colonoscopy through stoma; with biopsy, single or multiple	3.13	3.12	Colonoscopy through stoma	2.75	Biopsy	0.3	3.05	3.12
44390	Colonoscopy through stoma; with removal of foreign body	3.82	3.82	Colonoscopy through stoma	2.75	Foreign body	1.02	3.77	3.84
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	4.8
44403	Colonoscopy through stoma; with endoscopic mucosal resection	NA	5.81	Colonoscopy through stoma	2.75	Endoscopic mucosal resection	2.78	5.53	5.6

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base Procedure	Base RVU	Increment	Increment Value	Proposed WRVU	Finalized WRVU (Using 3.36 RVUs for the base)
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	3.12
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures	NA	4.41	Colonoscopy through stoma	2.75	Endoscopic ultrasound	1.38	4.13	4.2
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	0.84
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	1.15	1.14	Sigmoidoscopy	0.77	Biopsy	0.3	1.07	1.14
45332	Sigmoidoscopy, flexible; with removal of foreign body	1.79	1.85	Sigmoidoscopy	0.77	Foreign body	1.02	1.79	1.86
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance	1.46	1.15	Sigmoidoscopy	0.77	Submucosal injection	0.3	1.07	1.14
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination	2.6	2.43	Sigmoidoscopy	0.77	Endoscopic ultrasound	1.38	2.15	2.22

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base Procedure	Base RVU	Increment	Increment Value	Proposed WRVU	Finalized WRVU (Using 3.36 RVUs for the base)
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	2.91
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	2.82
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	NA	3.83	Sigmoidoscopy	0.77	Endoscopic mucosal resection	2.78	3.55	3.62
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure)	3.69	3.36	Colonoscopy	3.29				3.36
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45379	Colonoscopy, flexible; with removal of foreign body	4.68	4.37	Colonoscopy	3.29	Foreign body	1.02	4.31	4.38

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base Procedure	Base RVU	Increment	Increment Value	Proposed WRVU	Finalized WRVU (Using 3.36 RVUs for the base)
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple	4.43	3.66	Colonoscopy	3.29	Biopsy	0.3	3.59	3.66
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	4.19	3.67	Colonoscopy	3.29	Submucosal injection	0.3	3.59	3.66
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	5.34
45390	Colonoscopy, flexible; with endoscopic mucosal resection	NA	6.35	Colonoscopy	3.29	Endoscopic mucosal resection	2.78	6.07	6.14
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	4.74

(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. In the CY 2016 PFS proposed rule, we proposed to establish national pricing for CPT code 43775. To establish a work RVU, we crosswalked the work RVUs for this code from 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 proposed a work RVU of 20.38 for CPT code 43775.

Comment: Some commenters noted that CPT code 43775 was reviewed at the April 2009 RUC meeting and that the RUC submitted recommendations to CMS for CY 2010, including a recommendation of 21.40 work RVUs for CPT code 43775. The commenters stated that those recommendations are still valid and requested that CMS accept the RUC recommended work RVU of 21.40 for CPT code 43775.

Response: We thank the commenters for pointing out the previous RUC recommendations from April 2009. We continue to believe that the proposed work RVU is appropriate based on the reasons stated in the proposed rule, and therefore, for CY 2016, we are finalizing a work RVU of 20.38 for CPT code 43775.

Comment: A few commenters noted that they believe the crosswalk code used by CMS (CPT code 37217) does encourage relativity, but because it is an endovascular procedural code, does not accurately capture all aspects of a bariatric surgical patient in the pre-service, intra-service, or post-service periods. Commenters stated that they believed a comparison within the code family would provide an assessment that is more accurate. The commenters urged CMS to accept the previous valuation of 21.56.

Response: After consideration of the comments, we continue to believe that the proposed work RVU is appropriate based on the reasons stated in the proposed rule, and that it maintains

relativity within its family of codes. Therefore, for CY 2016, we are finalizing 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 proposed 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 proposed 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 change in input values, we also solicited comments 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 solicited comments 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 solicited 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 splenic flexure. 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.

Comment: Some commenters agreed with the proposed policy of using the -53 modifier to identify the reduced work involved with an incomplete colonoscopy and a reimbursement that is 50 percent of the full procedure. However, some noted that instances where the cecum is not reached immediately would be associated with greater PE than sigmoidoscopy, noting that the endoscopist will have utilized a colonoscope for the procedure requiring greater work for staff to clean and also noted that the endoscopist will commonly obtain a pediatric endoscope to navigate the narrowed sigmoid. Commenters also stated that sigmoidoscopy is a procedure commonly performed without moderate sedation. One commenter recommended that CMS establish a new

modifier for instances in which the colonoscope has passed beyond the splenic flexure but has not reached the cecum or small bowel – large bowel anastomosis due to inadequate preparation precluding high-quality examination of the lumen of the bowel or technical limitations that preclude the ability of the physician to safely complete the examination of the colon. The commenter also recommended that payment for the professional services for colonoscopy in these circumstances be adjusted to 75 percent of the payment for the colonoscopy procedure, noting that appending this new modifier to the professional services for the procedure would allow the same or other physician to bring the patient back for another colonoscopy examination within 2 months without triggering the frequency limitation under the Act, and that facility payment for the procedure would not be adjusted when this modifier is reported with codes 45378, G0105 or G0121.

Response: We appreciate the commenters' support for the proposed policy of using the -53 modifier. We also appreciate the additional feedback regarding the resource costs of incomplete colonoscopies and will consider whether further changes to valuation or the coding structure are necessary in future rulemaking.

(4) Malpractice (MP) Crosswalk

We examined the RUC-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 final rule with comment period 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-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-recommended MP crosswalks for these codes were likely to be more accurate than the RUC-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 those 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 are available, we proposed to use the specialty mix of the source code(s) in the RUC-recommended utilization crosswalk 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.

Comment: The RUC commented that they support CMS' decision to use the utilization crosswalk in determining the malpractice crosswalk for CPT code 43775 given that there are newer data since the RUC last reviewed this code in 2009. However, the RUC commented that it did not agree with this proposed decision for the other four services, CPT codes 44407, 44408, 46601, and 46607, stating that its MP crosswalks for these codes were based on the intended specialty mix.

Response: We continue to believe 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. Therefore, for CY 2016, we are finalizing these malpractice crosswalk codes as proposed.

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 on 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 proposed to establish values for the new codes based on RUC recommendations, subject to standard CMS refinements. We also note that because the invoices used to price the capital equipment included “on-board imaging,” and based on our review of the information used to price the equipment, we considered the costs of that equipment already to be reflected in the price per minute associated with the capital equipment. Therefore, we did not propose to include it as a separate item in the 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 proposed direct PE inputs for those codes were displayed the proposed direct PE input database available on the CMS website 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 direct PE inputs (and work RVUs and work time, as applicable) were displayed in proposed rule Addendum B on the CMS website.

We received many comments regarding various aspects of our proposal to implement the new CPT codes for radiation treatment services based on our refinement of RUC-recommended input values. Some commenters addressed issues for which we explicitly sought comment, while several commenters brought other issues to our attention. We address these comments in the following paragraphs.

(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 indicated that stereotactic guidance for radiation treatment services was furnished more frequently than CT guidance. The RUC recommended a work RVU of 0.58 and associated work times of three pre-service minutes, 10 intraservice minutes, and three 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. We solicited comments as to the appropriate work time associated with CPT code 77387.

Comment: Commenters provided feedback that work time of 16 minutes is accurate for 77387, consistent with the RUC recommendation without explaining why the work time associated with image guidance has changed significantly.

Response: We appreciate that commenters responded to our solicitation but the commenters did not provide a rationale for why the recommended work time for the new code would be significantly different than the current work time for the most frequently reported predecessor code. Absent an explanation, we remain concerned that the aspects of the recommended values for the new single modality code were developed based on erroneous assumptions regarding what imaging modality is most frequently used to provide guidance for radiation treatment services.

Although CPT codes 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). The RUC recommendation stated that the CPT editorial panel maintained CPT code 77014 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 included a statement that utilization of this code was expected to drop to negligible levels in 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.

Comment: Several commenters stated that, while they believe that the volume for 77014

will fall to negligible levels, they support CMS' adoption of the decision to continue to monitor and review this code.

Response: We appreciate commenters support and the stakeholder interest in making certain that the codes accurately describe the services furnished to Medicare beneficiaries.

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 CPT 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, stereotactic radiosurgery (SRS) or stereotactic body radiation therapy (SBRT) treatment delivery codes. The RUC recommendation, however, incorporated the same capital cost of image guidance equipment (a linear accelerator, or linac), for the conventional radiation treatment delivery codes and the the codes that describe IMRT treatment delivery services. The RUC explained that 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 for the proposed rule, we assumed 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 this 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, SRS, and SBRT treatment delivery codes as CPT guidance would suggest.

In order to avoid incorporating the cost of this equipment into both the treatment delivery codes (CPT codes 77402, 77407, and 77412) and the technical component of the new imaging guidance code (CPT code 77387-TC), we considered valuing CPT code 77387 as a professional service only and not creating the professional/technical component splits envisioned by CPT. In the proposed rule we stated that in the context of the budget neutral PFS, incorporating a duplicative direct input with a cost of more than six dollars per minute would have significant impacts on the PE RVUs for all other services. However, we also noted that the RUC did not address this issue in its recommendation and proposed that not all of the recommended direct PE inputs for the technical component of CPT code 77387 are capital equipment costs. Therefore, we proposed to allow for professional and technical component billing for these services, as reflected in CPT guidance, and to use the RUC-recommended direct PE inputs for these services (refined as described in Table 13 of the proposed rule (80 FR 41725-41764). We solicited comments on the technical component billing for image guidance in the context of the inclusion of a single linac and the RUC-recommended integration of imaging guidance technology for all external beam treatment codes.

Comment: Many commenters stated that it was necessary for CPT code 77387 to include both a technical and professional component because the current price of the linear accelerator used in radiation treatment delivery services does not include the additional costs of an integrated image guidance system. These commenters urged CMS to retain the technical and professional components for CPT code 77387 on the basis that there are equipment and labor costs associated with image guidance that are not reflected in a professional-only code.

Some other commenters were concerned that the new coding structure for image guidance did not accurately reflect the way that image guidance is typically furnished. These

commenters stated that multiple modalities of image guidance can be used in a single procedure, and that this heterogeneity is not reflected through a single image guidance code.

Response: We appreciate that many commenters addressed the bundling in the new CPT codes of the technical component of image guidance for IMRT, SRS, and SBRT, but not for conventional radiation treatment delivery codes. However, in reviewing the comments, we did not identify any that address the fundamental issues we identified in the proposed rule. We understand that commenters generally agreed that image guidance was not necessarily typically used for conventional radiation treatment delivery services, so the related costs should not be embedded in the RVUs for the treatment delivery codes. We also understand that commenters recommended that we assume that image guidance costs, while integrated into the functionality of the linear accelerator, represent additional capital costs and should be used in the development of PE RVUs for these services. Despite these comments, we were unable to reconcile the inconsistencies and potential rank order anomalies associated with including the image guidance costs in the IMRT treatment delivery codes but not including the image guidance costs in the conventional radiation treatment delivery codes even though both use the same capital equipment. Based on the RUC recommendations and the information from the commenters, we understand that the same linear accelerator is typically used for all of these services, and that the image guidance is integrated into the only linear accelerator that is currently being manufactured and that, therefore, the image guidance costs should always be included in the RVUs for the IMRT treatment delivery codes. Based on these comments and the RUC-recommended values, it appears that when the same machine (with integrated image guidance) is used for intermediate and complex conventional treatment, the combination of the treatment costs and image guidance costs is significantly higher than the technical costs associated with IMRT treatment delivery furnished with image guidance. As a result, the PE RVUs for these services include higher overall payment for intermediate and complex conventional radiation treatment with imaging

guidance than for simple IMRT treatment delivery with imaging guidance. After review of the comments, we continue to believe that this creates problematic rank order anomalies, both relative to the accuracy of the assumed costs and the financial incentives associated with Medicare paying more overall for conventional radiation treatment than for IMRT services.

Comment: Many commenters, including equipment manufacturers, suggested that linacs that include integrated image guidance are significantly more expensive than the \$2.6 million CMS proposed in the direct practice expense input database. One commenter, a manufacturer of linear accelerators, submitted several invoices intended to indicate that the price of a new linear accelerator is significantly higher than the current price in the direct PE input database. This commenter suggested that this higher price was due in part to the integrated image guidance, inherent in all new linear accelerators. The commenter also submitted invoices intended to illustrate the price of upgrading an older linear accelerator with image guidance capability.

Response: We appreciate the submission of invoices that indicate prices for linear accelerators with image guidance and the price associated with updating existing linacs with image guidance. In our analysis of these documents, however, we identified several aspects that make us hesitant to use the documents to change the price of the equipment in the direct PE input database. First, many of the invoices listed a total contract value that was distinct from the sum of total prices listed on the invoice. The documents themselves did not include any explanation regarding the significant differences in value between these two prices and whether or not the differences in value represent costs related to other direct PE input equipment items, factors already incorporated into the equipment cost per minute calculation, or items included in the allocation of indirect PE. For example, some line items included the description of items such as “travel and lodging,” “education,” and treatment planning software or software upgrades that are already accounted for in the allocation of indirect PE. In many cases line-item prices were not included, making it difficult to identify the portion of the total invoice price attributable to direct

equipment costs, which is necessary under the established PE methodology. Therefore, we will maintain the current equipment price for CY 2016 while we seek accurate information regarding the price of this capital equipment.

(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 would be 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 percent, 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/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 by the RUC, 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, we suggested in the proposed rule that 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. As we noted in the proposed rule, 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 proposed 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 proposed 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 how often the equipment is used in comparison to the previous assumption. In the proposed rule, we noted 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.

Comment: Several commenters objected to our analysis specifically because we described it as a “rough reconciliation.”

Response: We appreciate commenters’ interest in our use of the best data available in determining what values to assign to necessary assumptions. We regret the use of the term “rough reconciliation” and clarify that our analysis relied on two somewhat imprecise data points: the RUC procedure time assumptions for individual services and the current 50 percent utilization assumption. Because both of these assumptions directly determine how capital equipment costs are translated into PE RVUs, they were essential to our analysis. However, we recognize that these assumptions are round figures, reflecting assumptions about what is typical. Therefore, when we combined these numbers with precise Medicare claims data in order to develop a more accurate assumption, we arrived at a very specific number that might have appeared to be very precise. Recognizing that the calculation was based on assumptions as noted above, we subsequently proposed to round the number to 70 percent instead of using the fractional result of the calculation. We continue to believe rounding to 70 percent is appropriate for the reasons stated above.

Given the best available information, we believe that the 70 percent utilization assumption based on the changes in direct PE input recommendations and Medicare claims data 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 are 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 assumptions (7 hours out of 10 available business hours per day).

For advanced diagnostic imaging services, we finalized a policy for CY 2010 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 noted in the proposed rule 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 assumed that the transition to use of a single kind of capital equipment would likely take place over seven years as individual pieces of equipment age into

obsolescence. However, in the case of this transition in capital equipment, we have reason 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 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 proposed to use the 2013 recommendations for the CY 2016 PFS payment rates, we believed 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 recognized 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 the RUC and that the useful life of the newest generation of linear accelerator is seven 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 proposed to use a 60 percent utilization rate assumption for CY 2016 and a 70 percent utilization rate assumption for CY 2017. The proposed PE RVUs displayed in Addendum B on the CMS website were calculated using the proposed 60 percent equipment utilization rate for the linac as displayed in the proposed 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.

Comment: Most commenters were opposed to changing the default utilization assumption for linear accelerators. Many of these commenters stated that the rationale CMS used to support the change in default utilization assumption was inadequate and anecdotal. Several commenters performed and submitted their own data analyses.

Response: We continue to believe a reconciliation of Medicare claims data with the RUC-recommended procedure times results in the most accurate equipment utilization rate assumption. We also believe that whenever possible we should use the Medicare claims data to test the validity and internal consistency of our ratesetting assumptions. We do not agree with the commenters that such an approach is anecdotal. While CMS appreciates the analyses performed by some commenters, no additional data were submitted to substantiate these analyses.

Comment: One commenter conducted an analysis somewhat similar to ours, but used three data sets: Medicare claims data, the ASRT staffing survey CMS referenced in the proposed rule, and data from the CMS physician billing public use database. Based on this analysis, the commenter suggested that 50 percent is a more accurate utilization assumption.

Response: We appreciate the commenter's analysis, and found it to be very useful in considering whether or not to finalize our proposal. However, the commenter's conclusion of a 50 percent utilization rate is entirely dependent on what we believe is an overestimate of the number of linacs used to deliver radiation treatment. In order to determine the number of linacs overall, the commenter multiplied the 2.3 linacs per center statistic cited in the ASRT staffing survey by the number of individual billing entities reporting treatment services in the Medicare claims data as a proxy for the number of freestanding centers. That approach would count two radiation oncologists reporting services in the same center as if they were practicing in two centers, not one, and therefore overestimate the number of machines. Were the same analysis

conducted using the number of centers included in the same ASRT staffing survey, the result of the analysis would be an approximately 70 percent equipment utilization rate. Therefore, we did not find the commenter's analysis persuasive.

Comment: Many commenters stated that a 70 percent utilization rate assumption did not take into account events beyond the control of the facility that could impact how long any given linear accelerator might be used over the course of time. These commenters suggested that issues such as time necessary to warm up the treatment machine, maintenance, patient preferences, missed appointments, and multiple treatment devices contributed to a lower utilization rate that CMS proposed to assume.

Response: We understand that the day-to-day operation and utilization of capital equipment will vary, and that is precisely why the equipment cost per minute calculation does not assume that the equipment is used for the full amount of time possible (100 percent rate). Instead, the utilization rate assumption is used to allocate the total cost of the equipment relative to other direct PE costs on a per-minute basis. Therefore, the assumptions are intended to reflect the percentage of total time (assuming a 50-hour work week) payment is made for services on the machine. In assigning minutes to individual codes, we generally assign minutes for preparing and cleaning the equipment; therefore, these minutes would contribute to the 70 percent portion, or 35 hours per week. In contrast, minutes for a missed appointment would count toward the 30 percent of the 50 hours, or 15 hours per week, that the equipment is not being used.

Comment: Many commenters were concerned that a higher utilization rate assumption would have a negative effect on rural treatment centers and treatment centers in medically disadvantaged areas.

Response: We believe it is important to preserve access to care for all Medicare beneficiaries. However, we believe we are obligated under the statute to use accurate

assumptions in developing RVUs for individual services under the PFS. Under the statutory construct of the PFS, we believe that accurate valuation for all PFS services is important in maintaining access to care for all Medicare beneficiaries.

Comment: A few commenters suggested that CMS should phase in the utilization rate change over four years or delay implementing the change until 2017.

Response: We appreciate the commenters' suggestions. We did consider these suggested alternatives as part of our rulemaking process. Although both a longer phase-in and a delay would temporarily mitigate the payment reductions for these services, especially in the context of other proposed payment reductions, we did not identify any persuasive rationale for delaying implementation or phasing in implementation over more than 2 years.

Comment: Many commenters were concerned that the change in utilization rate assumption was affecting all equipment items in the radiation treatment delivery codes, and argued that it should only apply to the linac. Commenters urged CMS to use a 50 percent utilization rate assumption for the other equipment items. Some commenters argued that this was contradictory to the utilization assumption for advanced diagnostic imaging.

Response: We applied the increased utilization rate assumption across all equipment items under the assumption that items generally located in the same room as the linear accelerator could not be used to furnish other services while the linear accelerator was in use, and therefore, would be subject to the same utilization assumptions. This approach is consistent with the application of the equipment utilization assumption for advanced diagnostic imaging.

Comment: MedPAC expressed support for CMS' proposal to change the equipment utilization rate assumption for linear accelerators. MedPAC agreed that CMS should develop a normative standard based on the assumption that those who purchase an expensive piece of capital equipment would use it at a higher utilization rate.

Response: We appreciate MedPAC's support for the proposal.

(3) Other Equipment Cost Variables

Comment: A few commenters suggested that CMS update the price for the radiation treatment vault to approximately \$800,000 and reduce the useful life assumption from 15 to 7 years. Several other commenters suggested that CMS update the variable maintenance rate from the default five percent assumption to between 10 and 15 percent.

Response: We appreciate the commenter's feedback, and acknowledge our longstanding concerns regarding obtaining accurate, objective information regarding the pricing of direct PE inputs, particularly the prices for expensive equipment. In the case of the radiation treatment vault, we believe that at least some portions of the costs associated with the vault construction are indirect PE under the established methodology. We will continue to consider this issue, including these commenters' suggestion to use increased pricing for the item.

Comment: Many commenters disagreed with the classification of "intercom" as an indirect PE. These commenters stated that the intercom is specifically for the practitioner to communicate directly with the patient and, as such, it constitutes a direct PE.

Response: We remind the commenter that under the established methodology, direct PE inputs are defined as clinical labor, disposable supplies, and medical equipment. Other items are incorporated as indirect costs, regardless of how the items are used.

Comment: Several commenters, including the AMA RUC, stated that CMS should include 2 minutes for the clinical labor task "dose output and verification" as it is performed on the equipment items associated with these codes.

Response: "Dose output and verification" occurs during the "pre-service" period and pre-service minutes are generally not allocated to the equipment items, under our established methodology.

(4) Specialty Impacts

Comment: One commenter stated that CMS should no longer display specialty level

impacts for “radiation therapy centers” in the proposed and final rule. The commenter argued that since the PFS allowed charges associated with “Radiation Therapy Centers” represent only a small portion of radiation oncology services overall, displaying the impacts separately is misleading to the interested public.

Response: We appreciate the commenter’s concerns and agree with commenters that the PFS allowed charges associated with “radiation therapy centers” is only a small portion of overall payments for radiation oncology services, including the total amount of those furnished outside of the hospital setting. Because we think it is important to maintain a consistent display of specialty-level impacts between a proposed and final rule, we are not making a change for this year’s final rule. However, we are seeking additional comment regarding how the impacts for these services should be displayed in future rulemaking.

(5) Implementation of New Coding

Comment: Several commenters expressed concerns about the two new treatment delivery codes describing simple and complex IMRT treatment delivery in contrast to the current single code. Specifically, these commenters were concerned that that the CPT instruction that requires treatment for prostate and breast cancer to be reported using the simple IMRT treatment delivery code would have a negative impact on overall treatment for patients with prostate and breast cancer. These commenters suggested that that the new coding structure did not allow radiation therapy providers to accurately report prostate and breast cancer treatment services that are more resource intensive than those described in the simple IMRT code. These commenters also stated that the coding change including CMS’ proposed valuations would have a widespread negative impact on access to care, including reduction in the number of freestanding centers offering radiation treatment for breast and prostate cancer, and therefore limit patients’ access to care outside of the higher cost hospital setting.

Response: We believe that increased specificity in coding for such a resource-intensive,

high-volume group of services is a significant improvement compared to the use of a single code to describe all IMRT treatment services, regardless of their relative resource costs. However, we understand the commenters' concerns about the potential negative impact of implementing the new code set for payment of treatment for breast and prostate cancers. The primary resource cost for these services is represented by the capital equipment, so we believe that for purposes of most accurate payment, the optimal coding for these services would group them based on how long the capital equipment is being used per service, so that payment is linked to the resource costs of furnishing particular services. Under the current set of codes, payment would be made based on the assumptions regarding the typical resource costs for the treatment of particular diseases, instead of the resource costs based on the length of treatment time.

Comment: Several commenters pointed out a rank order anomaly in the PE RVUs among codes CPT codes 77402, 77407, and 77412 that describe simple, intermediate, and complex radiation treatment codes, respectively. The commenters stated that it was illogical for the intermediate radiation treatment delivery code to have higher PE RVUs and overall payment compared to the complex radiation treatment delivery. Commenters suggested that this anomaly may be the result of the allocation of indirect PE because the specialty reporting the utilization for the intermediate code is more frequently dermatology than radiation oncology and dermatology is allocated more indirect PE within the PE methodology.

Response: We agree with commenters that this rank order anomaly is due to the difference in the mix of specialties in the utilization for these services. We also agree with the commenters that such rank order anomalies within families should be avoided when possible. We believe these kinds of rank order anomalies generally suggest inaccurate valuations and present risks to accurate billing and overall ratesetting. The risks are associated with incentives toward inaccurate downward coding. For example, in this case, individual practitioners would have the financial incentive to report radiation treatment delivery services using the intermediate

code, even when the complex code would be more accurate. If practitioners acted on such an incentive, there would be serious consequences within our ratesetting methodologies for both purposes of budget neutrality and for allocation of PE RVUs. The increased utilization of the higher paying intermediate code would result in inappropriately low budget neutrality adjustment across the PFS. The rank order anomaly might also result in cyclical fluctuations in the year-to-year allocation of PE. This would happen if the inappropriate reporting of the intermediate code itself resulted in a concentration of most of the overall volume (including radiation oncology at a greater volume than dermatology) in the intermediate code. Then, once the claims data reflecting this concentration were incorporated into PFS ratesetting, the rank order anomaly would recur and the cycle would begin again. In considering these comments in the context of our proposal to implement these codes, we considered how we might eliminate this anomaly. We concluded that the best approach would be to maintain the total number of PE RVUs for these services overall, but to redistribute them among the three codes in order to eliminate the rank order anomaly. In order to do this, we would calculate the PE RVUs for these services under the established methodology and multiply these RVUs by the volume associated with each code. We would then reallocate the total number of PE RVUs among the three codes based on the weights of their direct costs included in the direct PE input database, since the total direct costs for these codes reflect appropriate valuation. We are seeking comment on this approach or other possible ways to mitigate the impact of the rank order anomaly among these codes.

Comment: One commenter stated that, in light of the significant negative impact of the coding changes and the proposed change in the default utilization rate assumption, CMS should delay implementation of the new codes for another year and work with stakeholders to gather information on the appropriate pricing of equipment items, utilization of equipment, and coding structure. A few commenters also stated that CMS should consider pricing radiation treatment delivery through the OPFS. And finally, several commenters noted that the proliferation of TC-

only codes had a negative impact on the overall allocation of PE RVUs for radiation oncology services.

Response: We agree with commenters regarding the magnitude of changes that would result from the new code set. In general, we believe that significant changes in coding can improve the valuation and payment for PFS services. In the case of this set of new codes, we believe increased granularity in IMRT treatment delivery codes would benefit payment accuracy. We also believe that it is generally preferable for CMS to use CPT codes to describe physicians' services paid under the PFS and that, when possible, we should use consistent coding between the PFS and OPFS.

In consideration of comments from stakeholders and our concerns as described above, however, we do not believe that, on balance, we should finalize the new code set for CY 2016. Therefore, for CY 2016, we are not finalizing our proposal to implement the new set of codes. We will continue the use of the current G-codes and values for CY 2016 while we seek more information, including public comments and recommendations regarding new codes to be developed either through the CPT process or through future PFS rulemaking. We believe that significant changes to the codes need to be made before we can develop accurate payment rates under the PFS for these services. These changes would include: developing a code set that recognizes the difference in costs between kinds of imaging guidance modalities; making sure that this code set facilitates valuation that incorporates the cost of imaging based on how frequently it is actually provided; and developing treatment delivery codes that are structured to differentiate payment based on the equipment resources used.

While we are not finalizing the new code set for these services, we are finalizing our proposals to include the single linear accelerator for radiation treatment delivery services as recommended by the RUC, and to update the default utilization rate assumption for linear accelerators used in radiation treatment services from 50 to 70 percent, phased in over 2 years.

Under either set of codes, it is clear that the 50 percent utilization assumption is incompatible with the times used to develop payment rates for individual procedures, given that the same linear accelerator is used for the services.

Finally, because the costs of capital equipment are the primary drivers of RVUs and payment amounts for these services, and we acknowledge significant difficulty in obtaining quality information regarding the actual costs of such equipment across the wide range of practitioners and suppliers that furnish these services, we will be engaging in market research to develop independent estimates of utilization and pricing for linear accelerators and image guidance used in furnishing radiation treatment services. We will also consider ways in which data collected from hospitals under the OPSS may be helpful in establishing rates for these and other technical component services. We will consider this information, including public comment, as we develop proposals for inclusion in future notice and comment rulemaking.

(6) Superficial Radiation Treatment Delivery

In the CY 2015 PFS final rule with comment period, we noted that changes to the CPT prefatory language modified the services that are appropriately billed using 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 CPT code 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 work and PE components for CPT 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 CPT code 77401, and practitioners were precluded from reporting these activities separately, additional 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 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. Finally, stakeholders 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.

In response, we solicited recommendations from 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. We believe it would be appropriate to address the clinical labor assigned to the code in the context of the information regarding the work that might be associated with the service. We also solicited information on the possible inclusion of nurse time for this service as part of the comments and/or recommendations regarding work for the service. Lastly, we reviewed the invoices submitted in response to our request to update the capital equipment for the service.

We proposed to update the equipment item ER045 “orthovoltage radiotherapy system” by renaming it “SRT-100 superficial radiation therapy system” and update the price from \$140,000 to \$216,000, on the basis of the submitted invoices. The proposed PE RVUs displayed

in Addendum B on the CMS website were calculated with this proposed modification that was displayed in the CY 2016 direct PE input database.

Comment: Multiple commenters from various specialty societies responded to our request for comment. Several stated that there was work in 77401, while other commenters stated that there was not. One commenter suggested that CMS create a G-code to account for work, while another commenter stated that 77401 should be resurveyed by the RUC.

Response: Given the disagreement among commenters on the work involved in furnishing CPT code 77401, we are considering the possibility of creating a code to describe total work associated with the course of treatment for these services and are seeking additional information on alternative descriptions and valuations for a code describing this work for consideration in future rulemaking.

Comment: A few commenters pointed out that the description of equipment item ER045 as proposed, “SRT-100 superficial radiation therapy system,” is a particular item that might better be identified generically as “superficial radiation therapy system.”

Response: We agree with the commenter’s suggestion and have updated the direct PE input database accordingly.

Comment: A few commenters thanked CMS for updating the price of the superficial radiation therapy system.

Response: We appreciate the support for our proposal.

After considering the comments, we are finalizing the update to ER045 as proposed.

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.

In the CY 2016 PFS proposed rule, for CY 2016 we proposed 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 proposed to adopt the RUC-recommended values (work RVUs, time, and direct PE inputs) for CPT codes 99497 and 99498 beginning in CY 2016. The services could be paid on the same day or a different day as other E/M services. Physicians’ services are covered and paid by Medicare in accordance with section 1862(a)(1)(A) of the Act. Therefore, under our proposal CPT code 99497 (and CPT code 99498 when applicable) would 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 E/M of these two diseases, including adjusting medications as appropriate. In addition to discussing the patient's short-term treatment options, the patient may express 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 solicited comment on this proposal, including whether payment is needed and what type of incentives the proposal might create. In addition, we solicited 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.

We received approximately 725 public comments to the proposed rule regarding payment for ACP services. We received comments from individual citizens; several coalitions; professional associations; professional and community-based organizations focusing on end-of-life health care; healthcare systems; major employers; and many individual healthcare professionals working in primary care, geriatrics, hospice/palliative medicine, critical care, emergency medicine and other settings. We also received comments from chaplains, ethicists, advanced illness counseling companies and other interested parties. The majority of commenters expressed support for the proposal, providing recommendations on valuation, the types of professionals who should be able to furnish or bill for the services and the appropriate setting of

care, intersection with existing codes, the establishment of standards or specialized training, and beneficiary cost sharing and education. Some commenters opposed or expressed provisional support for the proposal because they believed it might create perverse financial incentives relating to termination of patient care. We summarize all of the comments below.

Valuation

Comment: Many commenters supported the separate identification and payment for ACP, either by adopting CPT codes 99497 and 99498 or other unique code(s). Many commenters supported the proposal broadly, advocating for improved Medicare coverage and payment of ACP. Several commenters supported our proposal to adopt the RUC-recommended payment inputs. Several other commenters stated the proposed payment amount was insufficient, and one of these commenters recommended a payment rate equal to the payment for CPT code 99215 (Office or other outpatient visit for the E/M of an established patient) in order to appropriately account for the physician's time.

Response: We appreciate the commenters' support for separate identification and payment for voluntary ACP services. We believe the RUC-recommended inputs accurately reflect the resource costs involved in furnishing the services described by CPT codes 99497 and 99498, and therefore, are finalizing our proposal to adopt the RUC-recommended values for both codes.

Comment: Regarding the time required to furnish ACP services, the commenters cited times ranging from 10 minutes to several hours over multiple encounters, depending on the setting and the patient's condition. Several commenters requested payment for increments of

time of less than 30 minutes (for example, 10-15 minutes). One said the services typically require 30-45 minutes of face-to-face time with the patient and family. Several commenters recommended payment for services lasting less than 30 minutes, for example, by pro-rating the add-on code.

Response: We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services.

Comment: Many commenters recommended that CMS issue a national coverage decision to avoid any local variation in coverage.

Response: We believe it may be advantageous to allow time for implementation and experience with ACP services, including identification of any variation in utilization, prior to considering a controlling national coverage policy through the National Coverage Determination process (see 78 FR 48164, August 7, 2013). By including ACP services as an optional element of the AWW (for both the first visit and subsequent visits), as discussed below, this rule creates an annual opportunity for beneficiaries to access ACP services should they elect to do so.

Comment: Many commenters recommended limits on utilization to prevent abuse, while others recommended no utilization limits in order to increase access and ensure periodic updates to advance care plans. Several commenters were concerned that the lack of utilization limits would lead to practitioners harassing patients.

Response: In general, we do not agree with the commenters who suggested that this service is more likely to be subject to overutilization or abuse than other PFS services without our adoption of explicit frequency limitations. We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore, we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services. Since the services are by definition voluntary, Medicare beneficiaries may

decline to receive them. When a beneficiary elects to receive ACP services, we encourage practitioners to notify the beneficiary that Part B cost sharing will apply as it does for other physicians' services (except when ACP is furnished as part of the AWV, see the discussion below). We plan to monitor utilization of the new CPT codes over time to ensure that they are used appropriately.

Intersection with Other Services

Comment: Many commenters supported our proposal to pay for ACP services when furnished either on the same day or a different day than other E/ M services. Several commenters asked CMS to specify whether and how the ACP codes could be billed in conjunction with E/M visits or services that span a given time period, such as 10- or 90-day global codes or Transitional Care Management (TCM) and Chronic Care Management (CCM) services. One commenter recommended that CMS unbundle ACP services from critical care services and pay at a higher rate, but did not suggest an alternative payment amount.

Response: We believe that CPT guidance for these codes is consistent with the description and recommended valuation of the described services. When adopting CPT codes for payment, we generally also adopt CPT coding guidance. In this case, CPT instructs that CPT codes 99497 and 99498 may be billed on the same day or a different day as other E/M services, and during the same service period as TCM or CCM services and within global surgical periods. We are also adopting the CPT guidance prohibiting the reporting of CPT codes 99497 and 99498 on the same date of service as certain critical care services including neonatal and pediatric critical care.

Who Can Furnish/Setting of Care

Comment: Many commenters who supported the proposal provided recommendations regarding which practitioners and support staff should be able to provide or be paid for ACP services. Many commenters sought clarification regarding who would qualify as the “other

health care professionals” described by or able to bill the CPT codes. Many commenters described ACP services as being routinely provided by a multidisciplinary team under physician supervision. For example, they stated that ACP is routinely provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary’s treating provider. They stated that often a team approach is used, involving coordination between the beneficiary’s physicians, non-physician practitioners (such as licensed clinical social workers or clinical nurse specialists) and other licensed and credentialed hospital staff such as registered nurses.

Similarly, other commenters described social workers, clinical psychologists, registered nurses, chaplains and other individuals as appropriate providers of ACP services, either alone or together with a physician, and recommended payment for the services of these individuals. For example, one commenter stated that a significant portion of ACP discussions occur between patients and registered nurses or allied health professionals functioning as care coordinators, care navigators or similar roles; that a growing proportion are performed at home; and that CMS should enable care coordinators and navigators to bill the ACP codes either by defining them as “other qualified health professionals” or under “incident to” provisions.

Some commenters specifically recommended allowing social workers and chaplains qualified under the hospice benefit to bill the ACP codes. One community oncologist association stated that best practices have evolved to include a multi-disciplinary approach utilizing trained physician, advanced practice provider and social worker skill sets, and that nearly half of their oncology network’s ACP is performed by licensed clinical social workers. This commenter stated that while it is typical for a physician to initiate the ACP discussion with patients, ACP usually occurs with a mid-level provider or social worker and therefore the association requested that CMS allow clinical social workers to bill for these services. Another national association stated that it was working towards the development of new CPT codes for

practitioners such as social workers who the commenter believed would not be able to directly bill the proposed codes.

Some commenters argued that such non-medically trained individuals are qualified and have special training and expertise (whether psychosocial, spiritual or legal) that are needed on ACP care teams. Some believed that ACP is sometimes appropriate for physicians to perform, but that physicians do not have enough time to supply all of the demand for ACP services. Some commenters similarly argued that inclusion of social workers and other non-medically trained individuals including Spiritual Directors, Chaplains, Clinical Pastoral Counselors and others would alleviate concerns about undue influence over patient decisions. These commenters stated that part of the ACP conversation is emotional and spiritual and not merely clinical, so it is important to include individuals who can address the non-clinical aspect of ACP. Some commenters argued that widening the field of professionals who can initiate these conversations within their scope of practice will further encourage appropriate and frequent ACP. Several commenters stated that physicians should not be paid for ACP services due to an ethical or financial conflict of interest, and that communities should take more responsibility for these services.

In contrast, several commenters were concerned that allowing ACP to be paid to certain trained facilitators would undermine physician authority in treating patients. These commenters described the use of trained facilitators in certain community models that offer group discussions by trained lay and health professionals. These commenters were concerned that such facilitators would qualify as “other qualified professionals” under the CPT code descriptor and be given control over ACP, shaping physician behavior. One commenter stated that to prevent coercion of patients, it would be better if payment was limited to non-employees of hospitals.

Response: We appreciate the many comments we received on existing or recommended practice patterns for the provision of ACP services. We acknowledge the broad range of

commenters that stated that the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498. We note that as a physicians' service, "incident to" rules apply when these services are furnished incident to the services of the billing practitioner, including a minimum of direct supervision. We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision. We also note that the usual PFS payment rules regarding "incident to" services apply, so that all applicable state law and scope of practice requirements must be met in order to bill ACP services.

Comment: Several commenters recommended that CMS not require direct supervision for ACP services or allow it to be furnished "incident to" under general supervision.

Response: As discussed above, we understand that the services described by CPT codes 99497 and 99498 can be provided by physicians or using a team-based approach where, in addition to providing a minimum of direct supervision, the billing physician or NPP manages, participates and meaningfully contributes to the provision of the services. We note that the "incident to" rules apply when these services are provided incident to the billing practitioner, including direct supervision. We do not believe it would be appropriate to create an exception

to allow these services to be furnished incident to a physician or NPP's professional services under less than direct supervision because the billing practitioner must participate and meaningfully contribute to the provision of these face-to-face services.

Comment: Many commenters made recommendations regarding the settings of care that would be appropriate for payment of ACP services. Some of these commenters specified that payment should be made in both ambulatory and inpatient settings. Many commenters stated that ACP is ideally performed in a primary care setting, where the patient has a longstanding relationship with a physician and can engage in planning prior to illness, at which time they may be most receptive and most likely to have full decision making capacity. However many commenters believed payment was also appropriate in inpatient and other acute care settings. A few commenters recommended payment for an outpatient code or a code that would not be payable in the intensive care setting. Some commenters recommended that ACP should only be payable in clinical settings and that CMS should explicitly exclude group information sessions and similar offerings. Commenters stated that patients should be able to choose any location for ACP services including at home; in community-based settings; or via telehealth, telephone or other remote technologies. A few commenters were concerned that CMS might limit payment to certain specialists and recommended against such a policy.

Response: We agree with commenters that ACP services are appropriately furnished in a variety of settings, depending on the condition of the patient. These codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. We refer commenters to the CY 2016 hospital outpatient prospective payment system final rule with comment period for a discussion of how payment will be made to hospitals for ACP services furnished in hospital outpatient departments.

Comment: Many commenters supported payment for ACP along the entire health continuum, in advance of acute illness, and revisiting the advance care plan with changes in the

patient's condition. These commenters stated ACP is a routine service that should be regularly performed like preventive services. These commenters responded affirmatively to our solicitation as to whether or not ACP services should be included as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Several of these commenters specified that ACP should remain separately paid even if included as an optional element of the AWV.

Response: We appreciate the response of commenters regarding our request for comment on whether or not we should include ACP as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Based on the commenters' positive response to this solicitation, we are adding ACP as a voluntary, separately payable element of the AWV. We are instructing that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV.

Regarding who can furnish ACP when it is furnished as an optional element of the AWV, we note that AWV cannot be furnished as an "incident to" service since the AWV has a separate, distinct benefit category from "incident to" services. However, the current regulations for the AWV allow the AWV to be furnished under a team approach by physicians or other health professionals under direct supervision. Therefore, the rules that apply to the AWV will also apply to ACP services when furnished as an optional element of the AWV, including the requirement for direct supervision.

Comment: We received several comments requesting that ACP be added as a billable visit for FQHCs, and several comments requesting that we ensure that Medicare Administrative Contractors (MACs) are aware that a standalone ACP counseling session with an FQHC billable provider qualifies as a “billable visit” under Medicare’s Prospective Payment System (PPS) for FQHCs.

Response: RHCs and FQHCs furnish Medicare Part B services and are paid in accordance with the RHC all-inclusive rate system or the FQHC PPS. Beginning on January 1, 2016, ACP will be a stand-alone billable visit in a RHC or FQHC, when furnished by a RHC or FQHC practitioner and all other program requirements are met. If furnished on the same day as another billable visit, only one visit will be paid. Coinsurance will be applied for ACP when furnished in an FQHC, and coinsurance and deductibles will be applied for ACP when furnished in an RHC. Coinsurance and deductibles will be waived when ACP is furnished as part of an AWW. Additional information on RHC and FQHC billing of ACP will be available in sub-regulatory guidance.

Standards/Training

Comment: Many commenters recommended that CMS establish standards or require specialized training as a condition of payment for ACP services. Many commenters recommended standards or special training in relevant state law and advance planning documents; content and time; communication, representation, counseling, shared decision making and skills outside the scope of physician training. Several commenters recommended standards regarding the use of certified electronic health record technology; contractual or employment relationships with nurses, social workers and other clinical staff working as part of an ACP team; use of written protocols and workflows to make ACP part of routine care; and working with professional societies and other organizations including the National Quality Forum and the Agency for Healthcare Research & Quality to establish quality standards for

clinician-patient communication and ACP that would be tied to payment. Many commenters recommended policies to ensure documentation and transmission of the results of ACP among health care providers. Some of these commenters encouraged CMS to use technology to enhance the use and portability of advance directives across care settings and state lines, or recommended a universal registry.

Several commenters were concerned about the nature of the services that would be payable under the proposed codes, noting that ACP should extend beyond education about advance directives and completing forms. Several recommended the development of content criteria or quality measures to ensure that ACP services are meaningful and of value to patients. Some commenters expressed concern about ensuring appropriate services were furnished as part of ACP. For example, they expressed concern that payable services would include mere group information sessions, filling out forms or similar offerings. One commenter recommended that CMS require some minimal element like one personal real-time encounter, whether face-to-face or by phone or telemedicine.

Response: Since CPT codes 99497 and 99498 describe face-to-face services, we do not believe it would be appropriate at this time to apply additional payment standards as we have for certain non-face-to-face services such as CCM services. We will continue to consider whether additional standards, special training or quality measures may be appropriate in the future as a condition of Medicare payment for ACP services. We note that we did not propose to add ACP services to the list of Medicare telehealth services, so the face-to-face services described by the codes need to be furnished in-person in order to be reported to Medicare.

Comment: Several commenters supported advance care planning between patients and clinicians, but expressed concern about the potential for bias against choosing treatment options involving living with disability, requiring physicians to discuss questionable treatment options (such as physician assisted suicide or other patient choices that might violate individual

physician ethics) and similar issues. Some commenters were concerned that patients might change their decisions once care was actually needed and be unable to override previous advance directives; or that the government would be making healthcare decisions instead of patients, physicians, and families.

Response: As discussed above, based on public comments we received, we believe the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach where ACP is provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We also note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes, is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498, and "incident to" rules apply when these services are provided incident to the services of the billing practitioner under a minimum of direct supervision. We agree with commenters that advance care planning as described by the new CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP, in addition to providing a minimum of direct supervision, to manage, participate and meaningfully contribute to the provision of the services. Also, we note that PFS payment rules apply when ACP is furnished incident to other physicians' services, including where applicable, that state law and scope of practice must be met. Since the ACP services are by definition voluntary, we believe Medicare beneficiaries should be given a clear opportunity to decline to receive them. We note that beneficiaries may receive assistance for completing legal documents from other non-clinical assisters outside the scope of the Medicare program. Nothing in this final rule with comment period prohibits beneficiaries from seeking independent

counseling from other individuals outside the Medicare program – either in addition to, or separately from, their physician or NPP.

Beneficiary Considerations

Comment: Several commenters suggested that CMS pursue waivers of cost sharing for ACP services or that cost sharing should vary by the condition of the patient.

Response: We lack statutory authority to waive beneficiary cost sharing for ACP services generally because they are not preventive services assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF); nor may CMS vary cost sharing according to the patient’s diagnosis. Under current law, the Part B cost sharing (deductible and coinsurance) will be waived when ACP is provided as part of the AWW, but we lack authority to waive cost sharing in other circumstances. We would recommend that practitioners inform beneficiaries that the ACP service will be subject to separate cost sharing.

Comment: One commenter recommended beneficiary education through Medicare & You, partnerships with senior advocacy groups and other means.

Response: We agree that beneficiary education about ACP services, especially the voluntary nature of the services, is important. We welcome such efforts by beneficiary advocacy and community-based organizations and will consider whether additional material should be added to the Medicare & You handbook to highlight new payment provisions for these voluntary services.

In summary, we are finalizing our proposal to assign CPT codes 99497 and 99498 PFS status indicator “A” with RVUs developed based on the RUC-recommended values. We are also adding ACP as an optional element, at the beneficiary’s discretion, of the AWW. We are also making the conforming changes to our regulations at §410.15 that describe the conditions for and limitations on coverage for the AWW.

We note that while some public commenters were opposed to Medicare paying for ACP services, the vast majority of comments indicate that most patients desire access to ACP services as they prepare for important medical decisions.

d. Valuation of Other Codes for CY 2016

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

CPT code 11750 appeared on the RUC's misvalued code screen of 10-day global services with greater than 1.5 office visits and utilization over 1,000. The Health Care Professional Advisory Committee (HCPAC) reviewed the survey results for valuing this code and determined that 1.99 work RVUs, corresponding to the 25th percentile survey result, was the appropriate value for this service. As discussed in the proposed rule, we indicated that we believed the recommendation for this service overstated the work involved in performing this procedure, specifically, given the decrease in post-operative visits. Due to similarity in service and time, we indicated that we believed a direct crosswalk from the work RVU for CPT code 10140 (Drainage of blood or fluid accumulation), which is also a 10-day global service with one post-operative visit, more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2016 we proposed a work RVU of 1.58 for CPT code 11750.

The following is a summary of the comments we received on our proposal.

Comment: One commenter disagreed with CMS' direct crosswalk of the work RVU from CPT code 10140 to CPT code 11750. The commenters suggested that CMS establish the RVU for this procedure consistent with the recommendation. Additionally, the commenter stated that the HCPAC recommendation accounted for the removal of one post-operative visit from the global period. The commenter also stated that CMS' proposed work RVU would have an intraservice work intensity similar to a level one E/M visit (99211), which suggests that the value is too low.

Response: In developing our proposed RVUs for this service, we reviewed codes with similar intra-service and total times, and identified CPT code 11760 (Repair of nail bed) and CPT code 11765 (Excision of nail fold toe). Since we believe that the crosswalk for CPT code 11750 has similar intensity, and our proposed RVU is consistent with these similar services, we

do not agree with the commenter who states that the proposed work RVU is inaccurate.

After consideration of comments received, we are finalizing a work RVU of 1.58 for CPT code 11750, as proposed.

(2) Bone Biopsy Excisional (CPT Code 20240)

In its review of 10-day global services, the RUC identified CPT code 20240 as potentially misvalued. Subsequent to this identification, the RUC requested that CMS change this code from a 10-day global period to a 0-day global period for this procedure. Based on 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. In the proposed rule, we stated that we did not believe the RUC recommendation accurately reflected the work involved in this procedure, especially given the decrease in intraservice time and post-operative visits relative to the previous assumptions used in valuing the service. Therefore, for CY 2016, we proposed a work RVU of 2.61 for CPT code 20240 based on the reductions in time for the service.

The following is a summary of the comments we received on our proposal.

Comment: Several commenters, including the RUC, recommended that CMS reconsider its decision not to accept the RUC's recommendation for CPT code 20240. The commenters noted that the service was last valued by the Harvard study over 20 years ago and the assumptions made at the time no longer reflect current practice as the survey respondents included fewer than 10 non-orthopedic surgeons. Commenters stated that podiatry is currently the dominant provider of the service. Commenters also stated that deriving a new proposed work RVU based on existing work RVUs would be misguided in this case.

The commenters also suggested that using a reverse building block methodology to convert a 10-day global code to 0-day global code by removing the bundled E/M services is inappropriate since magnitude estimation was used initially when establishing the work RVUs

for surgical codes. Several commenters indicated that CMS' proposed work RVU has inappropriately low work intensity and expressed concern about CMS' approach to global code conversion.

Additionally, the RUC expressed disagreement with CMS' decision to remove 6 minutes of clinical labor minutes for discharge management time from 0-day global services stating there is clinical staff time that needs to be accounted for; the commenter requested we include the 6 minutes of clinical labor time based on the standard clinical labor task "conduct phone calls/call in prescriptions."

Response: In proposing what we believed to be a more accurate value for CPT code 20240, we considered applying the intra-service ratio, which yielded a value of 2.52 RVUs; however we believed that value would have inadequately reflected the work involved in furnishing the service. Instead, we opted to use the reverse building block methodology to remove the post-operative visits, acknowledging the transition from a 10-day to a 0-day global period. We removed the RVUs associated with the visits (1.12 RVUs) from the RUC-recommended value of 3.73 RVUs and arrived at an RVU of 2.61, which we continue to believe accurately accounts for work involved in furnishing the service. While we generally understand that the work RVUs may not have been developed using a building-block methodology, and that the reverse building block methodology may not always be the best approach to valuing services, we do not agree that significant changes in the post-operative period should be ignored, especially since we note that the RUC uses magnitude estimation to develop recommended work RVUs in the context of survey data regarding the number and level of visits in the post-operative periods.

In terms of the clinical labor minutes associated with the discharge day management, we do not agree that the typical discharge work associated for this service or for others without work time for discharge day management would typically involve clinical staff conducting phone calls

regarding prescriptions. We are aware that some codes include the clinical labor minutes for discharge management even though the work time for these codes do not include time for discharge management. We are seeking comment on how we might address this discrepancy in future rulemaking.

After consideration of comments received, we are finalizing the proposed work RVU of 2.61 for CPT code 20240.

(3) Endobronchial Ultrasound (CPT Codes 31622, 31652, 31653, 31625, 31626, 31628, 31629, 31654, 31632 and 31633)

For CY 2016, the CPT Editorial Panel deleted one code, CPT code 31620 (Ultrasound of lung airways using an endoscope), and created three new codes, CPT codes 31652-31654, 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 RVUs 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 proposed to use those work RVUs for CY 2016.

For the newly created codes, the RUC recommended work RVUs of 5.00 for CPT code 31652, 5.50 for CPT code 31653 and 1.70 for CPT code 31654. In the proposed rule, we stated that we believe the RUC-recommended work RVUs for these services overstate the work involved in furnishing the procedures. In order to develop proposed work RVUs for CPT code 31652, we compared the service described by the code descriptor to deleted CPT codes 31620 and 31629, because this new code describes a service that combines services described by CPT code 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 31652's RUC-recommended intraservice time (INTRA

= 60 minutes) and the sum of CPT codes 31620 and 31629's current and CY 2015 intraservice times (INTRA = 70 minutes), respectively. This resulted in a proposed work RVU of 4.71. To value CPT code 31653, we used the RUC-recommended increment of 0.5 work RVUs between this service and CPT code 31652 to calculate for CPT code 31653 our proposed work RVUs of 5.21. Lastly, because the service described by new CPT code 31654 is very similar to deleted CPT code 31620, we stated that we believed a direct crosswalk of the previous values for CPT code 31620 accurately reflected the time and intensity of furnishing the service described by CPT code 31654. Therefore, we proposed a work RVU of 1.40 for CPT code 31654.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated they did not agree with CMS' calculations or methodology utilized in valuing these services. The commenters suggested that CMS' calculations were based on inconsistent data. One commenter stated the methodology outlined in the proposed rule had several flaws in the understanding of the new and deleted bronchoscopy codes and questioned what purpose the creation of the new bundled codes were designed to address.

Response: As we have addressed more broadly, when we do not believe that the RUC-recommended values adequately address changes in the time resources required to furnish particular services, we have used several methodologies to identify potential work RVUs. We examine the results of such approaches and consider whether or not these results appropriately account for the total work of the service. We continue to believe that the methodology used to calculate the proposed work RVU is the most appropriate methodology to use for these procedures.

Specifically, in considering CPT code 31652 in the context of similar codes, including CPT code 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes

tracheal/bronchial dilation as required)) and CPT code 31661(Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes) both of which have 60 minutes of intraservice time and RVUs of 4.88 and 4.50, we continue to believe that a work RVU of 4.71 is the most accurate valuation. For CPT code 31653, we continue to believe that maintaining the RUC-recommended 0.5 work RVU increment between 31652 and 31653 yields the most accurate value for CPT code 31653. For CPT code 31654, we note the direct crosswalk preserves the work RVU of 1.40 from the previous CPT code 31620, which was also an add-on code, and had more intraservice time. Therefore, after consideration of comments received, we are finalizing the work RVUs for CPT codes 31622, 31652, 31653, 31625, 31626, 31628, 31629, 31654, 31632 and 31633 for CY 2016 as proposed.

Comment: One commenter also expressed appreciation of CMS' acceptance of the RUC's PE recommendation for several codes in this family.

Response: We appreciate the support of the commenter.

Comment: In its comment, the RUC indicated that equipment items ES045 and ES016 were incorrectly included for 31652, 31653, and 31654 and that these items were replaced with new equipment codes. In the CY 2015 Technical Correction Notice (CMS-1612-F2), equipment item ES015 was included in 31654, and the clinical labor direct PE inputs for 31654 were omitted from the direct PE input database. Similarly, for CPT code 31629, the RUC indicated that CMS proposed 30 minutes for clinical labor tasks "assist physician in performing procedure" and "assist physician for moderate sedation", as included in the CY 2016 proposed direct PE input database, while the RUC had recommended 35 minutes. The RUC opined that since the 30 minutes displayed for CPT code 31629 was incorrect, all of the corresponding equipment times included discrepancies of 5 minutes. The RUC suggested that all equipment times should increase by 5 minutes, excluding the stretcher, which should remain 89 minutes as that equipment is not needed during the intraservice portion of the procedure. In addition, the

RUC suggested that the calculation of supply item “gas, oxygen” (SD084) would also be affected by the “assist physician” time and should be 105 liters, rather than 90 liters as currently indicated in the supply direct PE input CMS file.

Response: We agree with the RUC’s comments regarding the proposed direct PE inputs for these procedures; the resulting changes appear in the final direct PE input database for CY 2016.

(4) Intravascular Ultrasound (CPT Codes 37252 and 37253)

In the CY 2015 PFS proposed rule, a stakeholder requested that CMS establish non-facility PE RVUs for CPT codes 37250 and 37251. CMS sought comment regarding the setting and valuation of these services. In September 2014, these codes were referred to the CPT Editorial Panel. The CPT Editorial Panel deleted CPT codes 37250 and 37251 and created new bundled codes 37252 and 37253 to describe intravascular ultrasound (IVUS). The RUC recommended 1.80 RVUs for CPT code 37252 and 1.44 RVUs for CPT code 37253. The RUC also recommended new direct PE inputs for an IVUS catheter and IVUS system. CMS proposed to accept the RUC-recommended work RVUs for intravascular ultrasound.

Comment: Commenters expressed support for CMS’ proposed work and time values, as well as for updating the direct PE inputs.

Response: We appreciate commenters’ support, and we are finalizing these values as proposed.

(5) 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 surveyed 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 used the RUC recommendations to propose values for CPT codes 38571 and 38572, since the RUC recommended reductions in the work RVUs that correspond with marked decreases in intraservice time and decreases in total time. As discussed in the proposed rule, we did 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 proposed a work RVU for CPT code 38570 of 8.49, which reflects the proportional reduction in total time for this code and maintains the rank order among the three codes.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, indicated that CMS should use the recommended work RVU of 9.34 for CPT code 38570. Commenters stated that CMS used an erroneous calculation to derive the proposed work RVU of 8.49, with the use of time ratios being methodologically flawed due to an assumption that the existing time is correct, that physician intensity would remain constant for a service over a period of many years, and that different components of total time consisting of differing levels of physician intensity cannot be measured together. Commenters stated that using this rationale as the basis for not accepting the RUC recommendation was unprecedented and misguided.

Commenters also stated that the recommended work RVU of 9.34 was based on work time and a comparison to CPT codes 31239 (Nasal/sinus endoscopy, surgical; with

dacryocystorhinostomy) and 50590 (Lithotripsy, extracorporeal shock wave). Commenters indicated that the comparison to these codes confirmed that maintaining the current value for CPT code 38570 would be appropriate. A different commenter stated that the survey time for this procedure had increased to 280 minutes and included a hospital inpatient visit. This commenter also urged CMS to maintain the current work RVUs of 9.34 for CPT code 38570.

Response: We refer the reader to our earlier discussion about time ratios. We continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the procedure has changed significantly. In the case of CPT code 38570, we noted that the intraservice time was reduced by 50 percent, from 120 minutes to 60 minutes, and the total time was also reduced from 242 minutes to 220 minutes. We also noted that the other codes in the same family, CPT codes 38571 and 38572, reflected similar time reductions and consequently had reduced recommended work RVUs. We believe that in order to maintain relativity, it is appropriate to apply a similar reduction to the work RVUs of CPT code 38570.

We were unable to find mention of CPT code 31239 in the RUC recommendations for 38570. Therefore, we considered the values for the code as a potential rationale for using the RUC-recommended value for CPT code 38570. We concluded that CPT code 31239 has limited utility as a comparison, since its values appear to be an outlier among codes with similar characteristics. For example, all 25 of the other 10-day global codes with 60 minutes of intraservice time have a lower work RVU than CPT code 38570, most of them substantially lower, with CPT code 49429 (Removal of peritoneal-venous shunt) having the next highest work RVU of 7.44. We also do not agree with the comparison to CPT code 50590, since that code describes all of the work within a 90-day global period, and we do not believe that relativity between services would be preserved if we were to make direct work RVU comparisons between

10-day and 90-day global codes.

After consideration of comments received, we are finalizing our proposed work RVUs of 8.49 for CPT code 38570, 12.00 for CPT code 38571, and 15.60 for CPT code 38572.

(6) Mediastinoscopy with Biopsy (CPT Codes 39401 and 39402)

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, the CPT Editorial Panel concluded that the code had 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 39401 and 39402 to describe each of the two mediastinoscopy procedures.

We proposed to accept the RUC-recommended work RVU of 5.44 for code 39401 and to use the RUC-recommended crosswalk from CPT code 52235 (Cystourethroscopy, with fulguration), which accurately estimates the overall work for CPT code 39401. In the proposed rule, we disagreed with the RUC-recommended work RVU of 7.50 for CPT code 39402. We stated that the work RVU for CPT code 39401 establishes an accurate baseline for this family of codes, so we proposed to scale the work RVU of CPT code 39402 in accordance with the change in the intraservice times between CPT codes 39401 and 39402. We indicated that applying this ratio in the intraservice time to the work RVU of CPT code 39401 yielded a total work RVU of 7.25 for CPT code 39402. We also noted that the RUC recommendation for CPT code 39401 represented 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 39402 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 proposed a work RVU of 7.25 for CPT code 39402.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated that the use of intraservice time ratios was inappropriate for valuation of CPT codes. They indicated that CMS should instead use the RUC's recommended work RVU of 7.50, due to the difference in technical skill, physical/mental effort, and additional stress involved in the performance of CPT code 39402 relative to CPT code 39401. Commenters expressed the importance of using physician survey data and magnitude estimation to arrive at work RVUs.

Response: We refer the reader to our earlier discussions about the utility of time ratios in identifying potential work RVUs for PFS services. We note that when comparing the work RVUs for CPT codes 39401 and 39402, the work RVU for CPT code 39402 was higher than would be expected based on the difference in time between these two procedures, even considering the more difficult clinical nature of CPT code 39402. We continue to believe that the use of intraservice time ratios is one of several different methods that can be effectively employed for valuation of CPT codes. For this particular mediastinoscopy family, CPT codes 39401 and 39402 share identical preservice time, postservice time, and office visits. Based on this information, we continue to believe that the intraservice time ratio between the two codes is the most accurate method for determining the work RVU for this procedure.

Comment: Several commenters suggested that CMS should use the RUC-recommended work RVU of 7.50 for CPT code 39402 based on the use of a building block methodology. Commenters stated that the RUC arrived at this value by adding the work RVU of CPT code 39401 (5.44 RVUs) to one half of the work RVU of CPT code 32674 (4.12 RVUs). The resulting calculation of 5.44 plus 2.06 equaled 7.50 RVUs, exactly the same value recommended by the RUC and a proof of the accuracy of magnitude estimation.

Response: We believe that the use of the reverse building block methodology would result in a significantly lower valuation for CPT code 39402. The current CPT code used for a mediastinoscopy with lymph node biopsy is 39400, which has a work RVU of 8.05, and includes three postoperative visits in its global period (a 99231 hospital inpatient visit, a 99238 hospital discharge visit, and a 99213 office visit). CPT code 39402 does not include the hospital inpatient visit (0.76 RVUs) or the office visit (0.97 RVUs), and includes only half of the discharge visit (0.64 RVUs). If the work of these visits were removed from CPT code 39400, the result would be a work RVU of $8.05 - 2.37 = 5.68$. We believe that this work RVU understates the work of CPT code 39402, which is why we believe that a building block methodology would be less accurate than the use of the intraservice time ratio for this code family.

After consideration of comments received, we are finalizing our proposed work RVU of 5.44 for CPT code 39401 and 7.25 for 39402.

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

The RUC 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 maintain the current work RVU of 1.69 in spite of the reductions in intraservice and total times. We proposed to reduce the work RVU to 1.42, which reduces the work RVU by the same ratio as the reduction in total time.

We also proposed to refine the RUC-recommended direct PE inputs by removing the inputs associated with cleaning the scope.

The following is a summary of the comments we received on our proposals.

Comment: The RUC disagreed with the methodology CMS used to develop the proposed work RVUs stating that CMS' proposed methodology did not account for differences in pre-service or post-service time. The RUC also stated that different components of total time

(preservice time, intra-service time, post-service time, and post-operative visits) consist of differing levels of physician intensity and CMS' calculations did not appear to have been based on any clinical information or any measure of physician intensity.

Another commenter supported our efforts to identify and address such incongruities between work times and work RVUs, stating that when work time decreases, work RVUs should decrease comparatively, absent a compelling argument that the intensity of the service has increased sufficiently to offset the decrease in work time.

One commenter disagreed with CMS' proposed PE refinements for CPT code 46500 regarding the pre-service clinical labor time for the facility setting, clinical labor time related to setting up endoscopy equipment, clinical labor time and supplies related to cleaning endoscopy equipment, equipment time for item ES002, and clinical labor time associated with clinical labor task "follow-up phone calls and prescriptions". The commenter also disagreed with CMS' refinement of not including setup and clean-up time for the scope at the post-operative visit.

Response: We believe the total time ratio produces an RVU that is comparable with other 10-day global services. We note that CPT code 41825 (Excision of lesion or tumor (except listed above), dentoalveolar structures; without repair) and CPT code 10160 (Puncture aspiration of abscess, hematoma, bulla, or cyst) are similar 10-day global services that have comparable work RVUs. For CY 2016, we are finalizing our proposed value of 1.42 RVUs for CPT code 46500.

After reviewing the public comments that were submitted regarding direct PE inputs, we recognize that we mistakenly believed that a disposable scope was included as a direct PE input, when a reusable equipment item was actually included. As a result, we removed the clinical labor time associated with setting up and cleaning the scope. Since we made this refinement in error, we will restore the clinical labor time associated with setting up and cleaning the scope. We also agree with commenters regarding the time for clinical labor task "follow-up phone calls and prescriptions". Therefore, we are restoring the RUC-recommended clinical labor times for

“follow-up phone calls & prescriptions”, “setup scope (non-facility setting only)”, and “clean scope”. As a result of including the previously removed clinical labor time associated with the equipment input ES002 (anoscope with light source), we are increasing the equipment time for this code from 60 minutes to 70 minutes. We did not add the set-up and clean scope time to the post-operative visits, however, since the clinical labor time for post-operative visits across PFS services match the clinical labor for the associated E/M visits. We are seeking comment regarding whether or not we should reconsider that practice broadly before making an exception in this particular case.

(8) Liver Allotransplantation (CPT Code 47135)

The RUC 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 results 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 corresponds to the survey median result, as well as the exact work RVU for CPT code 33935 (Heart-lung transplant with recipient cardiectomy-pneumonectomy). In the proposed rule, we stated that we did not believe the RUC-recommended crosswalk was the most accurate from among the group of transplant codes. We noted that 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 corresponds to the 25th percentile survey result for CPT code 47135. Therefore, we proposed to increase the work RVU of CPT code 47135 to 90.00.

The following is a summary of the comments we received on our proposal.

Comment: The RUC stated that its original reference code is the most appropriate

comparator for this service and revising the work RVU for CPT code 47135 to 1.9 percent below the RUC's recommendation would be arbitrary and punitive. Another commenter stated that while they believed the RUC proposed valuation more accurately reflected the work involved, they appreciated the proposal to increase the work RVUs associated with liver transplants, and suggested that CMS accept the RUC-recommended direct PE valuations.

Response: As we stated in the proposed rule, CPT code 32854(Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) has very similar intra-service and total times, in addition to an identical work RVU (90.00) to the 25th percentile survey result. We continue to believe the proposed direct crosswalk from CPT code 32854 (Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) to CPT code 47135 results in the most accurate valuation. Therefore, for CY 2016 we are finalizing without modification our proposed work RVU of 90.00 for CPT code 47135.

(9) Genitourinary Catheter Procedures (CPT Codes 50430, 50431, 50432, 50433, 50434, 50435, 50693, 50694, and 50695)

For CY 2016, the CPT Editorial Panel deleted six CPT codes (50392, 50393, 50394, 50398, 74475, and 74480) that were commonly reported together, and created 12 new CPT codes, both to describe these genitourinary catheter procedures more accurately and to bundle inherent imaging guidance. Three of these CPT 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 proposed to use the RUC-recommended work RVU of 3.15 for CPT code 50430. We agreed 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. We began by making comparisons between the service times of CPT code 50430 and the other codes in the family in order to determine the appropriate proposed work RVU of each procedure.

In our proposal for CPT code 50431, we stated that we disagreed with the RUC-recommended work RVU of 1.42; we instead proposed a work RVU of 1.10, based on three separate data points. First, the RUC recommendation stated that CPT code 50431 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 suggested that this value reflected the total work for the service. Accordingly, we proposed 1.10 as the work RVU for CPT code 50431.

We employed a similar methodology to develop a proposed work RVU of 4.25 for CPT code 50432. The three previously established codes were combined in CPT code 50432; these had respective work RVUs 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 examined the valuation of this service relative to other codes in the family. The ratio of the intraservice time of 35 minutes for CPT code 50430 and the intraservice time of 48 minutes for CPT code 50432, applied to the work RVU of base code 50430 (3.15), results in a potential work RVU of 4.32. The total time for CPT code 50432 is higher than CPT code 50430 (107 minutes relative to 91 minutes); applying this ratio to the base work RVU results in a work RVU of 3.70. We utilized these data to inform our proposed crosswalk. In valuing CPT code 50432, we considered CPT code 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance), which has an intraservice time of 50 minutes, total time of 105 minutes, and a work RVU of 4.25. Therefore, we proposed to establish the work RVU for CPT code 50432 at the crosswalked value of 4.25 work RVUs.

In the proposed rule, we stated that according to the RUC recommendations, CPT codes 50432 and 50433 are very similar procedures, with CPT code 50433 making use of a

nephroureteral catheter instead of a nephrostomy catheter. The RUC valued the added difficulty of CPT code 50433 at 1.05 work RVUs compared to CPT code 50432. We proposed to maintain the relative difference in work between these two codes by proposing a work RVU of 5.30 for CPT code 50433 ($4.25 + 1.05$). Additionally, we considered CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy), which has a work RVU of 5.40 and an identical intraservice time of 60 minutes, but 14 additional minutes of total time (133 minutes compared to 119 minutes for CPT code 50433), which supported the difference of 0.10 RVUs. For these reasons, we proposed a work RVU of 5.30 for CPT code 50433.

As with the other genitourinary codes, we developed the proposed work RVU of CPT code 50434 in order to preserve relativity within the family. In the proposed rule, we stated that CPT code 50434 has 15 fewer minutes of intraservice time compared to CPT code 50433 (45 minutes compared to 60 minutes). We proposed to apply this ratio of 0.75 to the base work RVU of CPT code 50433 (5.30), which resulted in a potential work RVU of 3.98. We also considered CPT code 50432 as another similar service within this family of services, with three more minutes of intraservice time compared to CPT code 50434 (48 minutes of intraservice time instead of 45 minutes). We noted that applying this ratio (0.94) to the base work RVU of CPT code 50432 (4.25) 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 direct crosswalk, and proposed a work RVU of 4.00 for CPT code 50434. 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 50435, we considered how the code and work RVU would fit within the family in comparison to our proposed values for CPT codes 50430 and 50432. CPT code 50430 serves as the base code for this group; it has 35 minutes of intraservice time in comparison to 20 minutes for CPT code 50435. This intraservice time ratio of 0.57 ($20/35$) resulted in a potential

work RVU of 1.80 for CPT code 50435 when applied to the work RVU of CPT code 50430 (3.15). Similarly, CPT code 50432 is the most clinically similar procedure to CPT code 50435. CPT code 50432 has 48 minutes of intraservice time compared to 20 minutes of intraservice time for CPT code 50435. This ratio of 0.42 (20/48) applied to the base work RVU of CPT code 50432 (4.25) results in a potential work RVU of 1.77. We also considered two additional procedures to determine a proposed value for CPT code 50435. 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 50435, with a work RVU of 1.82. Accordingly, we proposed a work RVU of 1.82, a direct crosswalk from CPT code 36569.

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 50693, we proposed a work RVU of 4.21, which corresponds to the 25th percentile survey result. We stated in the proposed rule that we believed that the work RVU corresponding to the 25th percentile survey result provided a more accurate value for CPT code 50693 based on the work involved in the procedure and within the context of other codes in the family. We also indicated that 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, was an accurate crosswalk for CPT code 50693.

For CPT code 50694, we compared its intraservice time to the code within the family that had the most similar duration, CPT code 50433. This code has 60 minutes of intraservice time compared to 62 minutes for CPT code 50694. This is a ratio of 1.03; when applied to the base work RVU of CPT code 50433 (5.30), we arrived at a potential work RVU of 5.48. We also looked to procedures with similar times, in particular CPT code 50382 (Removal and replacement of internally dwelling ureteral stent), which has 60 minutes of intraservice time, 125

minutes of total time, and a work RVU of 5.50. We proposed a work RVU of 5.50, a direct crosswalk from CPT code 50382.

Finally, we developed the proposed work RVU for CPT code 50695 using three related methods. In the proposed rule, we stated that CPT codes 50694 and 50695 describe very similar procedures, with 50695 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 50695 than for CPT code 50694. Maintaining the 1.55 work RVUs increment, we noted that adding 1.55 to our proposed work RVU for CPT code 50694 (5.50) would produce a work RVU of 7.05 for CPT code 50695. We also examined the ratio of intraservice times for CPT code 50695 (75 minutes) and the base code in the subfamily, CPT code 50693 (45 minutes). The intraservice time ratio between these two codes is 1.67; when applied to the base work RVU of CPT code 50693 (4.21), we calculated a potential work RVU of 7.02. We also noted that CPT code 36481 (Percutaneous portal vein catheterization by any method) shares the same intraservice time as CPT code 50695 and has a work RVU of 6.98. Accordingly, to maintain relativity among this subfamily of codes, we proposed a work RVU of 7.05 for CPT code 50695 based on an incremental increase of 1.55 RVUs from CPT code 50694.

In reviewing the direct PE inputs for this family of codes, we refined a series of the RUC-recommended direct PE inputs in order to maintain relativity with other codes in the direct PE database. All of the following refinements refer to the non-facility setting for this family of codes. Under the clinical labor inputs, we proposed to remove the RN/LPN/MTA (L037D) (intraservice time for assisting physician in performing procedure) for CPT codes 50431 and 50435. This amounts to 15 minutes for CPT code 50431 and 20 minutes for CPT code 50435. Moderate sedation is not inherent in these procedures and, therefore, we indicated that we did not believe that this clinical labor task would typically be completed in the course of this procedure. We also reduced the RadTech (L041B) intraservice time for acquiring images from 47 minutes

to 46 minutes for CPT code 50694. This procedure contains 62 minutes of intraservice time, with clinical labor assigned for acquiring images (75 percent) and a circulator (25 percent). The time for these clinical labor tasks is 46.5 minutes and 15.5 minutes, respectively. The RUC recommendation for CPT code 50694 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 reduced the time for clinical labor tasks “acquire images” to 46 minutes to preserve the 62 minutes of total intraservice time for CPT code 50694.

With respect to the post-service portion of the clinical labor service period, we proposed to change the labor type for the task “patient monitoring following service/check tubes, monitors, drains (not related to moderate sedation)”. There are 45 minutes of clinical labor time assigned under this category to CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695. Although we agreed that the 45 minutes are accurate for these procedures as part of moderate sedation, we proposed to change the clinical labor type from the RUC-recommended RN (L051A) to RN/LPN/MTA (L037D) to reflect the staff that would typically be doing the monitoring for these procedures. Even though the CPT Editorial Committee’s description of post-service work for CPT code 50435 included a recovery period for sedation, we recognized in our proposal that according to the RUC recommendation, CPT codes 50431 and 50435 did not use moderate sedation; therefore, we did not propose to include moderate sedation inputs for these codes.

The RUC recommendation for CPT code 50433 included a nephroureteral catheter as a new supply input with an included invoice. However, the RUC recommendation did not discuss the use of a nephroureteral catheter in the intraservice work description. CPT code 50433 did 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 asked for feedback from stakeholders regarding the use of the nephroureteral catheter for CPT code 50433, but did not

propose to add the nephroureteral catheter as a supply item for CPT code 50433 pending this information. We also requested stakeholder feedback regarding the intraservice work description in 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. In our proposal we stated that we did 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 therefore proposed to replace equipment item “room, angiography” (EL011) with equipment item “room, radiographic-fluoroscopic” (EL014) for the same number of minutes. We requested 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. In the proposed rule, we stated that we believed that such a recommendation from the RUC concerning all of these codes could be useful in ensuring relativity across the PFS.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated that the CMS proposed work RVUs were based on a flawed methodology. Commenters stated that CMS ignored intensity measures, differences in patient population, and risk profile considerations between the genitourinary codes. These commenters indicated that they did not agree with the use of intraservice time ratios as a methodology for establishing work RVUs.

Response: We refer the reader to our earlier discussion about the utility of time ratios in identifying potential work RVUs. For this particular group of codes, we believe that establishing

CPT code 50430 as the baseline value and then using intraservice time ratios to maintain relativity of work RVUs results in accurate work RVUs for these services. We note that these refined work RVUs were supported in all cases by the use of crosswalks to existing CPT codes which we believe reflect similar intensity, which further supported the refined work RVUs

Comment: Several commenters indicated that the compelling evidence standard applied by the RUC for requiring an increase in valuation had been met for this code family, and therefore increased work RVUs were acceptable when compared to the previous group of genitourinary catheter procedures.

Response: We recognize that the RUC internal deliberations include rules that govern under what circumstances individual specialties can request that the RUC recommend CMS increase values for particular services. As observers to the RUC process, we appreciate having an understanding of these rules in the context of our review of RUC-recommended values. However, we remind the commenters that we are aware of such rules when we initially consider RUC recommendations. We are committed to preserving relativity between services across the entirety of the PFS, and believe that our proposed values best achieve that aim.

Comment: Several commenters disagreed with the use of crosswalks to other CPT codes provided by CMS. Commenters stated that the work between the codes was not comparable due to clinical differences between the genitourinary catheter codes and the procedures described in the crosswalk codes. Commenters specifically referenced the crosswalk that CMS selected for CPT code 50431 and stated that the CMS chosen crosswalk code does not have the same infectious considerations (bacteremia) or the magnitude of diagnostic considerations as CPT code 50431.

Response: In the resource-based relative value system, services do not have to be clinically similar in order to be comparable. Relative value units (RVUs) are comparable across services furnished by different medical specialties. We note as well that the crosswalk codes

referenced by the RUC in its recommendations are frequently not clinically similar to the CPT code under review. In the case of 50431, we note that our crosswalk to CPT code 49460 has identical intraservice time and total time with CPT code 50431, along with similar clinical intensity, suggesting that it has value as a point of comparison for this code. Furthermore, we did not establish a direct crosswalk between the work of these two codes, only using CPT code 49460 (which has a work RVU of 0.96 RVUs) as one of three separate data points. For our second data point, we wrote that the recommendation for CPT code 50431 stated that the new code described work previously performed 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. For our third data point, we observed that the minimum survey result had a work RVU of 1.10, which we believe accurately reflects the total work for this service. The survey minimum value of 1.10 RVUs was the method used to establish our proposed work RVU for this code. We refer readers to the discussion above in the Methodology for Establishing Work RVUs section for more information regarding the crosswalks used in developing values for this procedure.

After consideration of comments received, we are finalizing our proposed work RVU of 1.10 for CPT code 50431.

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.25 for CPT code 50432 and suggested that CMS accept the RUC-recommended RVU of 4.70. They indicated that CMS used a clinically dissimilar crosswalk, CPT code 31660, which consists of very different work, patient populations, and potential complications. Commenters also stated that CMS used a different combination of existing CPT codes in its building block valuation of the new code 50432, leaving out CPT code 50390. Commenters indicated that this was a mistake and the use of CPT code 50390 would be typical.

Response: As we mentioned previously, in the resource-based relative value system, services do not have to be clinically similar to be comparable. CPT code 31660 shares

intraservice time and total time values that are nearly identical to CPT code 50432, along with similar clinical intensity, so we continue to believe that it is an accurate crosswalk. We also do not believe that the use of CPT code 50390 would be typical in constructing a building block methodology for CPT code 50432. The new code is assembled through a combination of genitourinary catheter CPT code 50392 with injection CPT codes 74425 and 74475. We do not believe that CPT code 50390 would typically be included in this group as well, since the code descriptors for both 50390 and 50392 also include drainage and this service would not be performed twice. We believe that the new CPT code 50432 would be used for either the previously reported CPT codes 50390 or 50392 service, but not for both of them at once. In addition, the RUC has recommended that we assume that most of the procedures previously reported using CPT code 50392 would be reported using new CPT code 50432.

We note as well that our proposed work RVU for CPT code 50432 was supported by the use of two time ratios with CPT code 50430. Both the intraservice time ratio and the total time ratio suggested that a value below the RUC recommendation of 4.70 RVUs would be more accurate. After consideration of comments received, we are finalizing our proposed work RVU of 4.25 for CPT code 50432.

Comment: Several commenters stated that CMS should accept the RUC-recommended work RVU of 5.75 for CPT code 50433. While they agreed with CMS' use of the RUC-recommended increment of 1.05 RVUs relative to CPT code 50432, they did not agree with the CMS refined work RVU of CPT code 50432 itself. Some commenters also did not support the CMS crosswalk to CPT code 57155, which they stated had very different work, patient population, and potential complications.

Response: We agree that CPT code 50433 is accurately valued at 1.05 RVUs greater than CPT code 50432, which describes the additional work performed by placing a nephroureteral catheter relative to the work of placing a nephrostomy catheter. However, we continue to believe

that our proposed work RVU for CPT code 50432 is an accurate value for the reasons detailed above. With regard to our crosswalk, we maintain that relative value units are comparable across different medical specialties. CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) has an identical intraservice time of 60 minutes and 14 additional minutes of total time, along with similar clinical intensity, which support the difference of 0.10 RVUs when compared to CPT code 50433. After consideration of the comments received, we are finalizing a work RVU of 5.30 for CPT code 50433.

Comment: Several commenters requested that CMS adopt the RUC-recommended work RVU of 4.20 for CPT code 50434. Commenters disagreed with the methodology that CMS used to arrive at the proposed value of 4.00 RVUs, in particular the use of intraservice time ratios, and stated that the CMS crosswalk to CPT code 31634 (Bronchoscopy, rigid or flexible, with balloon occlusion) was inappropriate due to clinical dissimilarity.

Response: We refer the reader to our earlier discussion about intraservice time ratios. We found the identical result of 3.98 work RVUs for CPT code 50434 when we applied the intraservice time ratio to CPT codes 50432 and 50433. This lent further support to our proposed work RVU. With regard to our crosswalk, we note that in the resource-based relative value system, CPT codes do not have to be clinically similar to be comparable. CPT code 31634 shares the identical intraservice time with CPT code 50434 and serves as a direct crosswalk. After consideration of comments received, we are finalizing our proposed work RVU of 4.00 for CPT code 50434.

Comment: Several commenters made similar statements regarding the proposed work RVU for CPT code 50435, criticizing the use of intraservice time ratios with other codes in the genitourinary catheter family and disagreeing with the crosswalked CPT codes for being medically dissimilar.

Response: We refer the reader to our earlier discussion about intraservice time ratios and continue to believe that their use results in accurate work RVUs for this family of codes. We made use of an intraservice time ratio with both CPT code 50430 (the base code for the family) and CPT code 50432 (the most clinically similar code), which produced results of 1.80 and 1.77 RVUs, respectively. We also found two different crosswalks with identical intraservice time and very similar work RVUs, including CPT code 36569, with identical intraservice time, identical total time, and a work RVU of 1.82 RVUs. Although we maintain that relative value units are comparable across different medical specialties, CPT code 36569 does in fact describe a medically related procedure, with the insertion of a central venous catheter. After consideration of comments received, we are finalizing our proposed work RVU of 1.82 for CPT code 50435.

Comment: Commenters urged CMS to adopt the RUC-recommended work RVU, corresponding to the median survey work RVU of 4.60 RVUs for CPT code 50693. They stated that the placement of a ureteral stent requires more work than the placement of a nephroureteral catheter, and the 0.21 RVU differential proposed by CMS is insufficient to reflect the additional work difficulty of CPT code 50693.

Response: We are uncertain about which codes are being compared by the commenters, since the 0.21 RVU differential referenced by the commenters does not exist in the codes that appear to be discussed in the comment (50433). Since the commenters did not include the five digit CPT designation in their comparison, we are uncertain which code the commenters intended to discuss.

We continue to believe that a work RVU of 4.21, corresponding to the 25th percentile survey result, is the most accurate value for CPT code 50693. We believe that the ureteral stent procedures are clinically similar to the rest of the genitourinary catheter family, and the use of intraservice time ratios with these procedures provides an accurate method for determining relative values. We continue to believe that the work RVU of 4.21, corresponding to the 25th

percentile survey result, is further supported through our crosswalk to CPT code 31648 (Bronchoscopy, rigid or flexible, with removal of bronchial valve) which has similar times and a work RVU of 4.20. After consideration of comments received, we are finalizing our proposed work RVU of 4.21 for CPT code 50693.

Comment: Several commenters made statements similar to those mentioned previously regarding the work RVU for CPT code 50694, criticizing the use of intraservice time ratios with other codes in the genitourinary catheter family and disagreeing with the crosswalked CPT codes for being medically dissimilar.

Response: We refer the reader to our earlier discussion about intraservice time ratios and continue to believe that their use results in accurate work RVUs for this family of codes. We compared CPT code 50694 with 50433, the code within the family with the most similar intraservice time, which resulted in a potential work RVU of 5.48. We also found that CPT code 50382 had nearly identical intraservice time and total time, and a work RVU of 5.50. While we maintain that relative value units are comparable across different medical specialties, we do not agree with the commenters that CPT code 50382 is medically dissimilar from CPT code 50694. The former refers to the removal and replacement of a ureteral stent, while the latter refers to the placement of a ureteral stent. We believe that these codes describe very similar procedures, share the same patient population, and can serve as a direct crosswalk for the work RVU of each other. After consideration of comments received, we are finalizing our proposed work RVU of 5.50 for CPT code 50694.

Comment: A few commenters stated that their comments on CPT code 50695 are similar to those they had made previously about CPT code 50433. While they agreed that CMS was correct to maintain the RUC-recommended increment of 1.55 RVUs greater than the value of CPT code 50694, they did not agree with the CMS refined work RVU of 50694 itself.

Commenters also did not support the CMS crosswalk to CPT code 36481, which they stated had very different work, patient population, and potential complications.

Response: We agree that CPT code 50695 is accurately valued at 1.55 RVUs greater than CPT code 50694, which describes the additional work performed by the use of a nephrostomy tube. However, we continue to believe that the proposed work RVU for CPT code 50694 is an accurate value for the reasons detailed above. With regard to our crosswalk, we continue to believe that relative value units are comparable across services furnished by different medical specialties. CPT code 36481 (Percutaneous portal vein catheterization by any method) has an identical intraservice time of 75 minutes and 18 additional minutes of total time, but a lower work RVU (6.98 RVUs) than the one suggested by our incremental method. Commenters also did not discuss our use of an intraservice time ratio with the base code in this subfamily, CPT code 50693, which suggested a work RVU of 7.02. After consideration of comments received, we are finalizing our proposed work RVU of 7.05 for CPT code 50695.

Comment: Several commenters disagreed with the CMS proposal to eliminate the RN/LPN/MTA blend (L037D) of clinical labor for assisting the physician during procedures 50431 and 50435. The CMS rationale was based on the lack of moderate sedation taking place in these two procedures. However, commenters argued that these procedures do require monitoring for patient stability that the attending physician cannot provide. They urged that the RN/LPN/MTA blend would be most appropriate for these procedures.

Response: We are not aware of any other procedures in which there is a third assistant in the procedure room when moderate sedation is not being provided. We believe that the standard use of clinical labor staff would be typical when performing these procedures.

Comment: Commenters also disagreed with the CMS proposal to change the labor type for patient monitoring following service (not related to moderate sedation) from the RUC-recommended RN (L051A) to the RN/LPN/MTA blend (L037D). Commenters stated that

although use of the RN/LPN/MTA blend is standard for this clinical labor task, the RUC allows specialty groups to use an RN with justification, and that was the case here for these procedures since they involve invasive percutaneous solid organ interventions.

Response: After consideration of comments, we agree that the use of the RN (L051A) clinical labor is typical for patient monitoring following service (not related to moderate sedation) for these particular specialty groups. We will restore the recommended L051A labor type for this clinical labor task for CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695. We will also consider making a formal proposal regarding the most suitable type of clinical labor staff for this monitoring in future rulemaking.

Comment: CMS sought clarification regarding the use of the nephroureteral catheter (SD306) for CPT code 50433. CMS removed this supply from CPT code 50433 since it was not mentioned in the information about the survey included in the RUC recommendation. Commenters wrote to explain that the phrase “An 8 Fr nephroureteral stent is inserted with the distal pigtail in the bladder” is included in the description of work for CPT code 50433, and in the context of genitourinary and biliary procedures, the historic term “stent” has been used interchangeably with the term “catheter”. Commenters suggested that the nephroureteral catheter should be maintained as a supply item for this code and for CPT code 50434.

Response: We agree that the nephroureteral catheter should be maintained as a supply item for CPT codes 50433 and 50434, based on the presentation of this additional information. However, based on our analysis of the comments, we believe that our review of the RUC recommendations would be facilitated by consistent use of terminology throughout the information included in the recommendations.

Comment: Several commenters, including the RUC, disagreed with the CMS decision to replace the angiography room (EL011) with a fluoroscopic room (EL014) for the genitourinary catheter family of codes. Commenters stressed that the fluoroscopic room was incapable of 3-

axis rotational imaging, that it would require dangerous movement of the patient, and that it presented sterility concerns. Commenters further disagreed that use of the angiography room was typically limited to cardiovascular procedures. They suggested that looking at service utilization, rather than number of CPT codes, indicates that non-vascular interventional procedures together comprise more than 50 percent of utilization of a typical angiography room. Commenters also provided a list of the equipment found in an angiography room, and stated that everything other than the “Injector, Provis” would be typically utilized for the genitourinary catheter procedures. As a result, the commenters urged CMS to reverse the proposed refinement and restore the use of the angiography room for these codes.

Response: We continue to believe that the use of an angiography room would not be typical for these genitourinary catheter procedures. The new genitourinary catheter codes in this family are being constructed through the bundling of imaging guidance with previously existing genitourinary catheter procedures. With the exception of CPT code 50398, the direct PE inputs for the predecessor codes do not include the use of an angiography room. We do not have reason to believe the coding changes related to these procedures would necessitate the use of different technology in furnishing the services. While it is true that the angiography room was included as a direct PE input for some of the predecessor imaging services, such as CPT codes 77475, 77480, and 77485, the equipment times for these services were significantly shorter than the time included for the base procedures, where use of the room was not considered to be typical. Given the six fold increase in recommended time and the significantly higher expenses of the newly recommended equipment versus the equipment costs associated with the predecessor codes, we are seeking not only a rationale for the use of the angiography room, but also evidence that this room is typically used when these services are reported in the nonfacility setting.

Comment: One commenter disagreed with the CMS decision to refine the time for clinical labor task “Clean room/equipment by physician staff” (L041B) from 6 minutes to 3

minutes. The commenter stated that there had been a robust discussion of this topic at the RUC meeting, and the additional minutes are needed to clean fluids/equipment/etc.

Response: We continue to believe that the standard time of 3 minutes for this clinical labor task is more accurate for the genitourinary catheter family of codes. We do not believe that these procedures typically produce enough external fluids to justify 6 minutes for room cleaning.

Comment: Several commenters disagreed with the CMS refinement of supplies to remove those that were duplicative of the same supplies found in visit packs (SA048) and sedation packs (SA044). Commenters stated that the IV starter kit (SA019), endoscope cleaning and disinfecting pack (SA042), non-sterile gloves (SB022), sterile gloves (SB024), sterile surgical gown (SB028), and three-way stop cock (SC049) were not duplicative supplies, as they were used in addition to the supplies included in the packs. Commenters requested that these supplies be restored to the direct PE inputs for the genitourinary catheter codes.

Response: We agree with the commenters that three sets of sterile garments would typically be used for the three medical professionals performing the procedure. We are therefore restoring one pair of sterile gloves, one sterile surgical gown, one IV starter kit, and one three-way stop cock to these codes, consistent with the RUC recommendation. We do not believe that the use of two more pairs of non-sterile gloves (beyond the two pairs already included in the visit pack) would be typical for these procedures. With regards to the “endoscope cleaning and disinfecting pack”, our rationale was not that this supply was duplicative, but rather that its use would not be typical because the genitourinary catheter codes do not make use of an endoscope. We did not receive comments that suggested that supply item “endoscope cleaning and disinfecting pack” would typically be used.

After consideration of comments received, we are finalizing the direct PE inputs as proposed, with the addition of the nephroureteral catheter for CPT code 50433, the change in clinical labor type from L037D to L051A for patient monitoring following service (not related to

moderate sedation), and the additional four supplies detailed in the previous paragraph for CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695.

(10) Penile Trauma Repair (CPT Codes 54437 and 54438)

The CPT Editorial Panel 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 54437 describes a repair of traumatic corporeal tear(s), while CPT code 54438 describes a replantation, penis, complete amputation.

In the proposed rule, we stated that we disagreed with the RUC recommendation of 24.50 work RVUs for CPT code 54438. We indicated that a work RVU of 22.10, corresponding to the 25th percentile survey result, was 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 54437 was also valued using the 25th percentile. We found 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 proposed a work RVU of 22.10 for CPT code 54438.

Because CPT codes 54437 and 54438 are typically performed on an emergency basis, in the proposed rule, we questioned the accuracy of the standard 60 minutes of preservice clinical labor in the facility setting, as we suggested that the typical procedure would not make use of office-based clinical labor. We suggested, for example, the typical case would require 8 minutes to schedule space in the facility for an emergency procedure, or 20 minutes to obtain consent. We solicited further public comment on this issue from the RUC and other stakeholders.

The following is a summary of the comments we received on our proposals.

Comment: One commenter urged CMS to accept the RUC-recommended value for CPT code 54438 at 24.50 RVUs. This commenter argued that the RUC regularly accepts the median survey work RVU for one service and the 25th percentile survey result work RVU for another

when both are in the same code family, particularly when they diverge in length of time. The commenter also suggested that reducing the intensity of CPT code 54438 below its RUC-recommended value of 0.071 was inappropriate for such a complex and difficult procedure, with an unusual patient population that is often schizophrenic and prone to self-injury. This commenter emphasized using the RUC-supplied reference of CPT code 53448 as justification for the RUC-recommended work RVU.

Response: We appreciate the presentation of this additional information concerning the complexity and intensity of CPT code 54438. We agree that the unusual patient population for this procedure justifies a higher work RVU than the proposed value. After consideration of comments received, we are finalizing our proposed work RVU of 11.50 for CPT code 54437, and assigning the RUC-recommended work RVU of 24.50 for CPT code 54438.

(11) Intrastromal Corneal Ring Implantation (CPT Code 65785)

CPT code 65785 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.

In the proposed rule, we stated that we disagreed with the RUC recommendation of a work RVU of 5.93 for CPT code 65785. Although we appreciated the extensive list of other codes the RUC provided as references, we expressed concern that the recommended value for CPT code 65785 overestimated the work involved in furnishing this service relative to other PFS services. We did not find any codes 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 unlikely to be accurate.

As a result, we proposed a work RVU for CPT code 65785 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 65785. 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, 7 additional minutes of total time, and a work RVU of 5.28. In the proposed rule, we stated that we believed that CPT code 58605 was a more accurate direct crosswalk because it shares the same intraservice time of 30 minutes with CPT code 65785. Accordingly, we proposed a work RVU of 5.39 for CPT code 65785.

The RUC recommendation for CPT code 65785 included 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 believed were more likely to be typical since we assumed 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 proposed to establish a new supply code for “suture, nylon 10-0” and price that item at \$12.17 each. We welcomed comments from stakeholders regarding this supply item.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters indicated that CMS should reconsider its decision and accept the RUC-recommended work RVU of 5.93. These commenters stated that the intraservice time ratio used by CMS did not account for differences in preservice time, postservice time, or levels of

physician intensity. Commenters also disagreed with CMS' statement that there were no services with a comparable intraservice and total time that had a higher work RVU than the RUC-recommended value of 5.93 for CPT code 65785. The commenters supplied a list of seven CPT codes that have a work RVU higher than 5.93 RVUs.

Response: We continue to believe that the use of intraservice time ratios is one of several different methods that can be used to identify potential work RVUs. For this particular code, the RUC used a direct crosswalk to CPT code 67917 (Repair of ectropion; extensive) to set their recommended work RVU at 5.93 RVUs. We do not believe that that direct crosswalk was the most accurate way to value CPT code 65785, since code 67917 has an intraservice time that is 10 percent longer than the intraservice time of CPT code 65785 (33 minutes to 30 minutes). CPT code 67917 is a clinically similar code which the RUC used for its own valuation of CPT code 65785, making it an especially good choice for comparative purposes after applying a ratio to normalize the intraservice times. We continue to believe that the use of an intraservice time ratio resulted in the most accurate value, given the difference in time between the two codes.

As discussed in the proposed rule, all CPT codes with comparable time values and the same global period had lower work RVUs than the RUC-recommended work RVU of 5.93. While it is true that the seven codes provided by the commenters have work RVUs higher than 5.93 RVUs, we do not agree that these CPT codes are appropriate for comparative purposes with code 65785. CPT code 33768 is an add-on code (global ZZZ) that cannot be compared to a code with a 90-day global period such as 65785. CPT code 59830 is a Harvard-valued code that has not been subject to RUC review, has low utilization (2013 = 7 reported services), and 20 minutes fewer total time than CPT code 65785. CPT codes 66770 and 67145 are also Harvard codes which have not been RUC reviewed, and both have different intraservice times than 65785, 5 minutes and 10 minutes, respectively. CPT codes 67210 and 67220 are the only codes supplied by the commenters to be recently reviewed by the RUC, but both of them have only 15 minutes

intraservice time, limiting their utility for comparative purposes with the 30 minutes intraservice time assumed for CPT code 65785. Although we accept the commenters' point that other codes with work RVUs above 5.93 RVUs do exist, we do not agree that codes referenced by commenters have "comparable intraservice and total time" with CPT code 65785. We continue to believe that scaling the RUC's key reference code of 67917 by the intraservice time ratio between the two codes provides the most accurate value for CPT code 65785.

After consideration of comments received, we are finalizing the work RVU and the direct PE inputs for CPT code 65785 as proposed.

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

The RUC reviewed 10-day global services and 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. The RUC requested surveys and reviews of these services for CY 2016.

As discussed in the proposed rule, the RUC recommended a work RVU of 1.00 for CPT code 68801 and a work RVU of 1.54 for CPT code 68810. Although we proposed to use the RUC-recommended work RVU for CPT code 68810, we stated that the recommendation for CPT code 68801 did not best reflect 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. We proposed to accept the RUC's recommendation to remove the 99211 visit from the service but proposed to further reduce the work RVU for CPT code 68801 by removing the RVUs associated with CPT code 99211. Therefore, for CY 2016, we proposed 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. In the proposed rule, we stated that the RUC recommendations for these services do not appear to best reflect the work involved in performing these procedures. To value these services for the proposed rule, 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 produced the proposed work RVUs of 1.74, 2.70, and 2.10 for CPT codes 68811, 68815, and 68816, respectively.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, suggested that CMS reconsider its decision to not accept the RUC recommendations. The commenters believe that using a reverse building block methodology to reduce a work RVU for this service is inappropriate since magnitude estimation was used to establish the recommended work RVUs for this series of codes. Commenters also believe that CMS did not provide detailed rationale for the rejection of the RUC-recommended work RVUs for CPT codes 68811, 68815 and 68816. Finally, commenters noted that the existing IWPUT for each of these three surgical services is below 0.03, which the commenters believe calls into question the accuracy of the existing work time and its usage in deriving a new work RVU.

Response: We appreciate the commenters' perspectives, but reiterate that our proposed values accounted for the changes in the time resources assumed to be involved in furnishing these services since they were previously valued. We note that the validity of the IWPUT alone as a measure of intensity is reliant on the accuracy of the assumption regarding the number and level of visits for services in the global period for individual services. Therefore, we do not generally agree that a low IWPUT itself indicates misvaluation, particularly for services with global periods. After considering the comments received, we continue to believe that the work RVUs proposed for these codes accurately reflect the work involved in furnishing these services.

Therefore, for CY 2016 we are finalizing work RVUs for CPT codes 68801, 68810, 68811, 68815, and 68816, as proposed.

(13) Spinal Instability (CPT Codes 72081, 72082, 72083, and 72084)

For CY 2015, the CPT Editorial Panel deleted codes 72010 (radiologic examination, spine, entire, survey study, anteroposterior and lateral), 72069 (radiologic examination, spine, thoracolumbar, 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 72081, two to three views in 72082, four to five views in 72083, and minimum of six views in 72084.

In the proposed rule, we stated that we did not agree with the RUC's recommended work RVUs for the four new codes. For 72081, 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 RVUs in the source code and comparing that to the time and work RVU ratio in the new code. Using the relationship between time and RVUs from deleted CPT code 72069, we proposed a work RVU of 0.26 for CPT code 72081, 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 proposed to adjust the RUC-recommended work RVUs for CPT codes 72082, 72083 and 72084 to 0.31, 0.35, and 0.41, respectively.

The following is a summary of the comments we received on our proposals.

Comment: Many commenters, including the RUC, disagreed with CMS' proposed crosswalk for 72081 and urged CMS to use the RUC recommendation. The commenters stated that since CPT code 72069 is being deleted due to changes in technology and patient population,

it is a poor comparison. Other commenters pointed out that CPT code 72081 typically includes an X-ray of skull, cervical spine, and pelvis and therefore is by definition more work than CPT code 72069. CPT code 72069 is also noted as “CMS/other” code in the RUC’s time file and the times in that file are not divided into time periods as CPT code 72081 is. One commenter suggested that a more accurate crosswalk was CPT code 74020 (Radiologic examination, abdomen; complete, including decubitus and/or erect views,) which has a work RVU of 0.30. Using the same increments, the commenter suggested that the CMS proposed change for CPT code 72081 to 0.26 RVUs would result in an accurate increase in work across the family.

Response: We continue to believe that CPT code 72069 is an accurate crosswalk. While CPT code 72069 may not be divided into time periods, the ratio between the total time and the RVU adequately reflects the relationship between time and intensity in CPT code 72081. Although we used CPT code 72069 as a comparison to CPT code 72081, we note that CPT code 72081 has a higher work RVU, which accounts for the extra work associated with imaging the skull, cervical spine, and pelvis. We do not believe that CPT code 74020 would be an accurate crosswalk because it describes a radiological examination of the abdomen whereas CPT code 72069 refers to the same anatomical region as CPT code 72081.

Therefore, after considering the comments received, we are finalizing these work RVUs for 72081, 72082, 72083, and 72084 as proposed.

(14) 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. In the

proposed rule, we stated that we had concerns about valuation of this code since it is a guidance code used only for a single procedure, CPT code 58970 (aspiration of ova), and that these two codes are typically billed concurrently. We believe CPT codes 76948 and 58970 should be bundled to accurately reflect how the service is furnished.

We proposed 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 CPT code 58970. We proposed 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 work time of 30 minutes and an RVU of 0.56. Therefore we proposed to maintain 25 minutes of intraservice time for CPT code 76948 and proposed a work RVU of 0.56.

The following is a summary of the comments we received on our proposals.

Comment: Commenters stated that CMS should not have removed the work from the pre and post service portions of the service period and should restore the RUC-recommended work RVU of 0.85. The commenters stated that in the pre service period the physician reviews clinical history as well as prior imaging studies, and in the post service period the physician reviews and signs final report. The RUC commented that CPT codes 58970 and 76945 were billed less than 10 times each in 2014, and were not billed together in any of those instances. The RUC acknowledged that these codes may be billed together under private payers and stated they would continue to review codes billed together 75 percent of the time and bundle them when appropriate.

Response: We appreciate the commenters' feedback. However, given the definition of the codes, we continue to believe that CPT code 76945 is the image guidance code for CPT code 58970, and that these codes would not typically be billed separately. We acknowledge the anomalies in the low volume of Medicare claims data but do not believe that data likely reflects the way the services are intended to be reported. Therefore, any pre- or post-service work would

be accounted for in CPT code 58970. After considering the comments received, we are finalizing a work RVU of 0.56 for CPT code 76945 as proposed.

(15) Surface Radionuclide High Dose Radiation Brachytherapy (CPT Codes 77767, 77768, 77770, 77771, and 77772)

In October 2014 the CPT Editorial Panel created five new codes to describe high dose radiation (HDR) brachytherapy. We proposed the RUC-recommended work RVUs of 1.05, 1.40, 1.95, 3.80, and 5.40 respectively, for CPT codes 77767, 77768, 77770, 77771, and 77772. The RUC also recommended a new PE input, a brachytherapy treatment vault, which we proposed to include without modification.

Comment: Commenters expressed support for CMS' proposed work and time values for this family of codes, and for CMS' proposal to add the brachytherapy vault as a PE input. Many commenters expressed concern for the overall downward trend in reimbursement for brachytherapy services, citing a sustained decrease in office-based brachytherapy procedures since 2009. The commenters encouraged CMS to enact measures to improve this.

Response: We appreciate commenters' concerns regarding accurate payment for brachytherapy services. The revaluation of services under the Potentially Misvalued Code Initiative is aimed at achieving the most appropriate relative values under the PFS. There is not an intentional "downward trend" for any particular family of services. We remind commenters and stakeholders that disagree with CMS values, including those based on RUC recommendations, that in addition to submitting comments on our proposed rules, they may also nominate codes as potentially misvalued through the public nomination process. We are finalizing the values for HDR brachytherapy as proposed.

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

As discussed in the proposed rule, in establishing CY 2015 interim final direct PE inputs 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 recommendation 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 reexamined 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 proposed 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.

In establishing interim final work RVUs for this family of codes, we refined the RUC recommendation for CPT code 88341 to 0.42, such that the work RVU for this add-on code was 60 percent of that of the base code 88342 (0.70 work RVUs). We noted that for similar procedures in this family, the RUC had recommended work RVUs for add-on codes that were 60 percent of the base codes, and that we believed this methodology would appropriately value this add-on code. In the proposed rule, we reexamined the work RVU for this service in the context of reviewing the immunofluorescent studies procedures. In doing so, we increased the work RVU of this add-on code to 0.53, which reflected 76 percent of 0.70, the base code for this service. We discuss our rationale for this adjustment in the immunofluorescent studies section below. However, we inadvertently omitted the rationale for this revision to the work RVU in the proposed rule.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated their appreciation of CMS’ reconsideration when reexamining the RUC-recommended direct PE inputs, “UltraView Universal DAB Detection Kit” (SL488) and equipment time for the supply item “microscope,

compound” (EP024) for CPT codes 88341, 88342, and 88344 following feedback from the public.

A few commenters also noted that the work RVU for CPT code 88341(Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure) as displayed in Addendum B of the proposed rule was inconsistent with the CY 2015 work RVU but was not discussed elsewhere in the proposed rule.

Response: The discussion about the rationale for the increased work RVU for CPT code 88341 was inadvertently omitted from the proposed rule. Since the proposed rule did not include this discussion, we will maintain the interim final status of the CY 2015 work RVU of 0.53 for CY 2016 and we are seeking comment on this work RVU during the comment period for this final rule with comment period.

(17) Immunofluorescent Studies (CPT Codes 88346 and 88350)

For CY 2016, the CPT Editorial Panel deleted one code, CPT code 88347 (Antibody evaluation), created a new add-on service, CPT code 88350, 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 88350. In the proposed rule, we stated that although we proposed to use the RUC recommendation for CPT code 88346, we did not believe the recommendation for CPT code 88350 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 code 37250 (Ultrasound evaluation of blood vessel during diagnosis or treatment) and CPT code 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 88350. Due to these similarities, we believed it was 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 88350. In the proposed rule, we explained that we multiplied the RVU of CPT code 88346, 0.74, by 24 percent, and then subtracted the product from 0.74, resulting in a work RVU of 0.56 for CPT code 88350. Therefore, for CY 2016, we proposed a work RVU of 0.74 for CPT code 88346 and 0.56 for CPT code 88350.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated their disagreement with the comparison of immunofluorescent studies (CPT codes 88346 and 88350) to ultrasound evaluation of blood vessels (CPT Codes 37250 and 37251). Commenters specifically stated the ultrasound services are add-on services involving initial and additional vessels, whereas CPT codes 88346 and 88350 involve work related to initial and additional single antibody stain procedures. Commenters maintain that the level of work required to evaluate the initial stain is nearly identical to the second and that no efficiency is gained from the initial to the next and, therefore, a reduction in work RVUs for the additional slide would be inappropriate.

Response: We continue to believe that the RVUs should reflect a reduction of overall work in each additional antibody stain slide. We also note that for CY 2015, we established as interim final a 40 percent reduction for add-on codes, which we subsequently refined to a 24 percent reduction in the CY 2016 proposed rule. We have not received any alternative recommendations as to the appropriate value for CPT code 88350. Therefore, we are finalizing our proposed valuation for CPT codes 88346 and 88350.

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

The RUC reviewed and developed recommendations regarding CPT codes 88367 and 88368. We reviewed and proposed values based on those recommended values as discussed in

the proposed rule. Subsequently, the RUC 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 was identical to the RUC recommendation provided for CY 2015. Therefore, we proposed to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016.

For CPT codes 88364 and 88369, we refined the RUC recommendations to 0.67 for both procedures, such that the work RVUs for these add-on codes was 60 percent of the base codes. We noted that for similar procedures in this family, the RUC had previously recommended work RVUs for add-on codes that were 60 percent of the base codes, and that we believed this methodology would appropriately value these add-on codes. In the proposed rule, we reexamined the work RVUs for these services in the context of reviewing the immunofluorescent studies procedures. In doing so, we increased the work RVUs of these add-on codes to 0.67, which reflected 76 percent of 0.88, the work RVUs of the base codes for these services. We discuss our rationale for this adjustment in the immunofluorescent studies section above. However, we inadvertently omitted the rationale for this revision to the work RVU in the proposed rule.

As discussed in the proposed rule, 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.

For CY 2016, we reexamined these codes when valuing the immunofluorescence family of codes, and reviewed information received from commenters during the CY 2015 final rule’s comment period that described the typical batch size for each of these services, which identified apparent inconsistencies and discrepancies in the quantity of units among the codes in the family. For CY 2016, we proposed 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. 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 proposed 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. Therefore, we proposed to include this equipment item consistent with the RUC recommendations for CPT code 88366.

In the proposed rule, we noted 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 noted 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 expressed concern

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 noted in the proposed rule 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 noted that an equipment item involved in furnishing a service 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 invited stakeholders to provide us with information about the equipment and supply inputs used in the typical case for particular pathology services.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated their disagreement with the methodology utilized in valuing CPT code 88367 and urged CMS to use survey data and magnitude estimation when proposing a work RVU. Commenters also suggested that there should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence or any pathology service. One commenter noted that for CPT code 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure), using computer-assisted technology does not replace the pathologist's work; it merely refers to computer-aided selection of images for the pathologist to review and that the computer does not establish the distinction between cancer and non-cancer cells.

Response: As discussed in the CY 2015 final rule with comment period (79 FR 67669), we do not believe the RUC-recommended work RVU of 0.86 for 88367 (intraservice time = 25 minute) adequately reflects the difference in time relative to 88368 (RVU = .88, intraservice time = 30 minutes). Commenters did not address our concerns about this change in time not being reflected in the work RVU for 88367. Therefore, we continue to believe 0.73 RVUs accurately reflects the work for CPT code 88367. With regard to CPT code 88374, while we acknowledge using computer-assisted technology does not replace the pathologist's work, we continue to believe there are some efficiencies gained with the computer assistance. After considering the comments received, for CY 2016, we are finalizing the values for CPT codes 88367 and 88374 as proposed.

Comment: A commenter noted that the work RVUs for CPT codes 88364 and 88369 as displayed in Addendum B of the proposed rule were inconsistent with the CY 2015 work RVUs, but were not discussed elsewhere in the proposed rule.

Response: As noted above, the discussion about the rationale for the increased work RVU was inadvertently omitted from the proposed rule. Since the proposed rule did not include this discussion, we will maintain the interim final status of the work RVU of 0.76 for CPT codes 88464 and 88369 for CY 2016 and we are seeking comment on these work RVUs during the comment period for this final rule with comment period.

(19) Vestibular Caloric Irrigation (CPT Codes 92537 and 92538)

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, 92537 and 92538, to report caloric vestibular testing for bithermal and monothermal testing procedures, respectively. The RUC recommended a work RVU of 0.80 for CPT code 92537 and a work RVU of 0.55 for CPT code 92538. In the proposed rule, we stated that we believed that the recommendations for these services overstate the work involved in performing these

procedures. Due to similarity in service and time, we proposed that a direct crosswalk of CPT code 97606 (Negative pressure wound therapy, surface area greater than 50 square centimeters, per session) to CPT code 92537 accurately reflects the total work involved in furnishing the service. To establish a proposed value for CPT code 92538, we divided the proposed work RVU for 92537 in half since the code descriptor for this procedure describes the service as having two irrigations as opposed to the four involved in CPT code 92537. Therefore, for CY 2016, we proposed work RVUs of 0.60 to CPT code 92537 and 0.30 to CPT code 92538.

The following is a summary of the comments we received on our proposals.

Comment: Several specialty societies stated their disappointment that CMS did not accept the RUC-recommended work RVUs for CPT codes 92537 and 92538. Commenters stated their objection to the rationale CMS used, stating that the rationale ignored the cogent, methodical, and thorough approach utilized by the RUC.

Response: We appreciate the commenters' feedback. However, we reiterate that CPT code 97606 has nearly identical intra-service and total times as CPT code 92537 and given the similarity in services we continue to believe the direct crosswalk from CPT code 97606 to CPT code 92537 to be the most accurate. Also, CPT code 92538 describes two irrigations which is half the work involved in furnishing the service of CPT code 92537. For that reason, we continue to believe it is appropriate to establish 92538 with half of the work RVUs of 92537. Therefore, for CY 2016 we are finalizing a work RVU of 0.60 for 92537 and 0.30 for 92538.

(20) Instrument-Based Ocular Screening (CPT Codes 99174 and 99177)

For CY 2015, the CPT Editorial Panel created a new code, CPT code 99177, 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. In the proposed rule, we stated that CPT code 99174 was currently assigned a status indicator of N (non-covered service) which we proposed should remain unchanged since this is a screening

service. After review of CPT code 99177, we proposed that this service was also a screening service and should be assigned a status indicator of N (non-covered service). Therefore, for CY 2016, we proposed to assign a PFS status indicator of N (non-covered service) for CPT codes 99174 and 99177.

The following is a summary of the comments we received on our proposals.

Comment: A few commenters, including the RUC, stated their disagreement with CMS' proposal to assign a status indicator of "N" (non-covered service). Commenters stated there is a long-standing precedent that status indicator "N," codes have had their RUC-recommended values published in the PFS.

Response: We continue to believe CPT codes 99174 and 99177 are screening services and are therefore non-covered services under the Medicare program. Therefore, for CY 2016, we are finalizing our proposed assignment of a PFS status indicator of N (non-covered service) for CPT codes 99174 and 99177. Because we have not reviewed the recommended values for these services, we do not believe that we should develop or display RVUs for these services. In some cases in the past, we have developed and displayed RVUs for codes not separately payable by Medicare. However, we note that this practice has not been consistently applied and we have concerns about this practice since it is not apparent in the display itself that the resulting RVUs do not reflect our review or assessment of the recommendations nor do they reflect the influence of updated Medicare claims data. However, we understand that, for PFS nonpayable services, displaying RVUs that are based solely on recommendations may serve an interest for the public. Therefore, we will consider for the future how we might reconcile that interest with our interest in maintaining a clear distinction between the RVUs that result from our established methodology and RVUs that result solely from recommended input values.

(21) Lung Cancer Screening Counseling and Shared Decision Making Visit and Lung Cancer Screening with Low Dose Computed Tomography (CPT Codes G0296 and G0297)

We issued national coverage determination (NCD) for Medicare 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, effective February 5, 2015. The American College of Radiology (ACR) submitted recommendations for work and direct PE inputs.

We proposed to value CPT code G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)) using a crosswalk from the work RVU 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 one 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 G0296 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.

For CPT code G0297 (Low dose CT scan (LDCT) for lung cancer screening), the ACR recommended that CMS crosswalk CPT code G0297 to CPT code 71250 (computed tomography, thorax; without contrast material) with additional work added to account for the added intensity of the service. After reviewing this recommendation, we stated in our proposal that the work (time and intensity) was identical for both CPT code G0297 and CPT code 71250. Therefore, we proposed a work RVU of 1.02 for CPT code G0297. The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated that the CMS-proposed crosswalk for G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)) did not accurately reflect the time and intensity of furnishing this service. Some commenters suggested that 15 minutes is

not enough time for the practitioner to engage in a meaningful conversation with the patient and that the work and time for the shared decision making visit should reflect this.

Response: Because we continue to believe that the cognitive work for G0296 is comparable to G0443 and that there is no additional work associated with fulfilling the requirements of the NCD, we believe that the work and time for the counseling and shared decision making visit is included in the values associated with the crosswalk code.

Comment: For CPT code G0297 (Low dose CT scan (LDCT) for lung cancer screening), a few commenters expressed support for our proposed work RVUs of 1.02. Several commenters were concerned that the proposed crosswalks and work valuations did not adequately reflect the time and intensity involved in furnishing these services. The American College of Radiology suggested that a lung cancer screening low dose CT required greater technical skill and mental effort to make the correct diagnosis, and that the baseline increase of malignancy caused greater psychological stress for the provider and the additional requirements of the NCD add to the intensity of performing these services.

Response: Reading radiologists that meet the eligibility requirements of the NCD have extensive experience interpreting chest CTs. For example, the NCD states that among other things, an eligible reading radiologist must have been involved in the supervision and interpretation of at least 300 chest CT acquisitions in the past 3 years. Therefore, we do not believe that extra work is involved in furnishing the low-dose CT, as compared to CPT code 71250.

Comment: Several commenters requested CMS clarify that a medically necessary E/M visit can be billed on the same day as the lung cancer screening counseling and shared decision making visit. Some commenters also requested that the shared decision making visit be considered part of, or complementary to, the annual wellness visit. Several commenters also asked CMS to clarify that the lung cancer LDCT screening and the counseling and shared

decision making visit are not subject to cost sharing since they are preventive services.

Response: As long as the NCD requirements for the counseling and shared decision making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M visit or an annual wellness visit with the -25 modifier. Practitioners should refer to the NCD for information regarding the Medicare coverage requirements for the counseling and shared decision making visit. Lung cancer screening with LDCT, including a lung cancer screening counseling and shared decision making visit, is covered as an additional preventive benefit, identified for Medicare coverage through the NCD process. Therefore, this benefit meets the criteria in sections 1833(a)(1) and (b)(1) of the Act for nonapplication of the deductibles and coinsurance.

Comment: Many commenters were concerned with the fact that, although the NCD was issued in February of 2015, there are no instructions for billing services performed prior to 2016.

Response: CMS is in the process of developing claims processing, coding and billing instructions. This information is forthcoming.

Comment: One commenter asked if the imaging facility would be subject to recoupment for a CT if a hospital performed a CT believing that the required counseling had occurred, and later it was determined that it had not.

Response: We appreciate this comment. While we acknowledge the commenter's concern, we believe that this comment is outside the scope of this rulemaking.

Comment: One commenter requested that the shared decision making visit be added to the list of telehealth services.

Response: We refer readers to section II.I. of this final rule with comment period, where we discuss the process for adding services to the list of Medicare telehealth services. In addition, we note that information about how to submit a request to add a service to the telehealth list is available on the CMS Website at www.cms.gov/telehealth.

Comment: Commenters were concerned that there was a discrepancy in reimbursement between the PFS and the OPFS.

Response: Payments made under the PFS and the OPFS are established under different statutory provisions using different bases and methodologies, and therefore often result in differential payment amounts for similar services.

Comment: Several commenters pointed out that there were no malpractice or PE inputs for G0296 and G0297 in the downloads available with the proposed rule.

Response: We appreciate commenters' attention to detail and we have corrected these values in this final rule with comment period.

After consideration of the comments received, we are finalizing the work RVUs for G0296 and G0297 as proposed.

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 PE data that are auditable, comprehensive, and regularly updated would contribute to the accuracy of PE 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 RVUs, 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 reviewed the RUC-recommended direct PE inputs for these services and proposed to use them, with the refinements addressed in this section. However, we also identified 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 noted that while we proposed 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)

The RUC recommendation for CPT code 11760 included 22 minutes assigned to clinical labor task “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 were also calculated based on the 22 minutes of intraservice time. We proposed to use the RUC-recommended equipment times while we solicited comments on whether or not it would be appropriate to include the full 33 minutes of work intraservice time for the equipment.

Comment: A commenter clarified that the 22 minutes of time for clinical labor task “Assist physician in performing procedure” was indeed intended to represent 67 percent of the physician intraservice time of 33 minutes. The commenter agreed that it is appropriate to include the full 33 minutes of intraservice time in the equipment time calculation.

Response: We appreciate the clarification of this issue from the commenter. After consideration of comments received, we will refine the equipment times for CPT code 11760 by adding 11 minutes to each item, to reflect the entire intraservice period of 33 minutes.

Comment: One commenter disagreed with the CMS decision to remove pre-service clinical labor time in the non-facility setting. The commenter stated that the service is performed

more than 33 percent of the time in a facility setting, and suggested that CMS should adopt the RUC recommendation.

Response: We continue to believe that this clinical labor task would not be performed on a typical basis, as the procedure is most frequently done on an emergent basis. We also do not believe that time should be allotted for clinical labor task “Provide pre-service education/obtain consent” in the preservice period, since CPT code 11760 also includes time for the same clinical labor task in the service period. We note that information about the percentage of time a service is performed in one setting versus another is not factored into our assessment of PE inputs for each setting. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 11760, with the additional refinements to equipment time discussed above.

b. Simple Repair of Superficial Wounds (CPT Codes 12005, 12006, 12007, 12013, 12014, 12015, and 12016)

We refined the time for clinical labor task “Check dressings & wound/home care instructions” to 3 minutes for each code in this family to reflect the standard time for this clinical labor task.

Comment: One commenter stated that the commenter was unaware that there was a standard time for this clinical labor task. The commenter stated that a reduction to 3 minutes was not warranted absent an identified standard in this regard.

Response: Three minutes is the generally applied number of minutes assigned to the clinical labor task “Check dressings & wound/home care instructions”. In general, we continue to believe that this is the most accurate time for this clinical labor task.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 12005, 12006, 12007, 12013, 12014, 12015, and 12016.

c. Intermediate Repair of Wounds (CPT Codes 12041, 12054, 12055, and 12057)

We refined the preservice clinical labor time in the non-facility setting to zero minutes, and the information in the proposed rule indicated that this refinement was because these codes are emergent procedures where certain clinical labor tasks would not typically be performed. We also removed one of the two suture packs (SA054) from the recommended list of supplies, and adjusted the equipment time formulas to reflect the established standards.

Comment: A commenter disagreed with the CMS decision to remove the preservice clinical labor time in the non-facility setting. The commenter stated that neither the site of service nor the diagnosis codes for these services indicate that these are emergency procedures, and they are most commonly performed in a non-emergent setting. The commenter urged CMS to accept the RUC-recommended times for these clinical labor tasks.

Response: We appreciate the commenter bringing this issue to our attention. After reviewing these clinical labor activities again, we continue to believe that time for these preservice activities should not be included in the non-facility setting. However, our stated rationale for this refinement, that this is due to the emergent nature of these procedures, was incorrectly stated due to a clerical error. We intended to explain that we refined these preservice activities to zero minutes because the standard preservice clinical labor for 10-day global codes in the non-facility setting is zero minutes for all five preservice activities, and there was no additional justification to increase the value for this group of codes. We are maintaining this refinement to zero minutes.

Comment: One commenter indicated that CMS incorrectly reduced the quantity of suture packs (SA054) from two to one for CPT codes 12055 and 12057 in the facility setting. CMS stated that there was no rationale for the increase in the quantity of this supply and that sutures would only be removed one time, but the commenter stated that suture removal takes place twice for these procedures, with some of the sutures being removed at each of the two office visits. The commenter requested that CMS accept the RUC-recommended supply inputs.

Response: We appreciate the additional information regarding the use of suture packs for this procedure. After consideration of comments received and based on this presentation of new information, we agree that the second suture pack would typically be used in these procedures, and we are restoring the quantity of SA054 to two for CPT codes 12055 and 12057 in the facility setting.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 12041, 12054, 12055, and 12057, with the additional refinement to SA054 discussed above.

d. Nasal or Sinus Surgical Endoscopy (CPT Codes 31295, 31296, and 31297)

We refined some of the preservice clinical labor times to align with standard values, as well as the fact that the decision for surgery would have been made on the previous day. We also refined the time for clinical labor task “Sedate/apply anesthesia” to reflect the established standard, refined the quantity of the Afrin nasal spray (SJ037) to the amount typical for the procedures, and refined the equipment times to conform to our standard policies.

Comment: A commenter disagreed with the decision by CMS to refine the time for clinical labor task “Sedate/apply anesthesia” from 5 minutes to 2 minutes. The commenter stated that 5 minutes would be typical for these procedures, since a topical anesthesia requires additional time to be applied, the staff typically applies a local anesthetic after the initial topical form, and a second application is necessary in the majority of patients.

Response: We continue to believe that the established standard of 2 minutes for clinical labor task “Sedate/apply anesthesia” is the most accurate value for these procedures. The RUC recommendations for these codes did not provide a rationale for anesthesia times in excess of the standard value.

After consideration of comments received, we are finalizing the direct PE inputs for CPT codes 31295, 31296, and 31297 as proposed.

e. Removal of Embedded Foreign Body from Mouth and Pharynx (CPT Codes 40804 and 42809)

In the proposed rule, we stated that the ENT suction and pressure cabinet (EQ234) would not typically be used during an office visit, and we refined the equipment times to remove the minutes associated with the office visit. We also refined the quantity of supply item “suction canister” (SD009) from two to one to reflect the amount typically used during these procedures.

Comment: One commenter indicated that the suction and pressure cabinet would be standard in ENT rooms, and would be used to store items and equipment to keep them clean. The commenter urged CMS to accept the RUC-recommended equipment time for the suction and pressure cabinet.

Response: We include direct PE inputs for items and services that are typically involved in furnishing a particular service. The presence of the suction and pressure cabinet in the same room where the procedure is being performed does not provide sufficient rationale for its inclusion in this service since it is not typically used in furnishing the service. We continue to believe that the suction and pressure cabinet would only be utilized during the intraservice portion of CPT codes 40804 and 42809, and not during the follow-up office visits.

Comment: The same commenter stated that these procedures required the use of two suction canisters. The commenter explained that one suction canister would be used during the intraservice portion of the procedure, and the other suction canister would be used during a follow-up office visit.

Response: We continue to believe that the use of a suction and pressure cabinet would not be typical for an office visit, and therefore there is only a need for one suction canister for these procedures. Furthermore, the RUC considered this issue in making its recommendations, and found that no suction canister is needed in the follow-up visit for the service when furnished in the facility setting. We therefore do not believe that the suction and pressure cabinet, with a

corresponding suction canister, would be typically used during a follow-up visit when the procedure is furnished in the non-facility setting.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 40804 and 42809.

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

We proposed to update the price for supply item “Millipore filter” (SL502) based on stakeholder submission of new information following the RUC’s original recommendation. As requested, we proposed to crosswalk the price of SL502 from the cytology specimen filter (Transcyst) supply (SL041) and assign a price of \$4.15. The proposed direct PE inputs are included in the proposed CY 2016 direct PE input database, which is available on the CMS website under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. We also refined the time for clinical labor task “Order, restock, and distribute specimen containers with requisition forms” to zero minutes due to our belief that this task was not allocable to individual services and therefore an indirect PE under our established methodology.

As discussed in the proposed rule, 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 proposed 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 no slide preparation is taking place, as the descriptor for this code suggests.

We proposed to update supply item “protease solution” (SL506) based on stakeholder submission of new information following the RUC’s original recommendation. As requested, we proposed 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 direct PE input database, which is available on the CMS website under downloads for the CY 2016 final rule with comment period at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

Subsequent to receiving these recommendations, we received additional recommendations from the RUC for this family of procedures following the publication of the CY 2016 PFS proposed rule. We will address both recommendations here.

Comment: A commenter provided an invoice for supply item “Millipore filter” (SL502) to replace the current supply crosswalk to the cytology specimen filter (SL041).

Response: We appreciate the submission of this supply invoice. After consideration of comments received, we will update the price of supply item “Millipore filter” (SL502) in our direct PE inputs database from the current value of \$4.15 to the submitted invoice price of \$0.75.

Comment: A commenter stated that the clinical labor task “Order, restock, and distribute specimen containers with requisition forms” is a direct PE as it is a variable clinical labor task.

The commenter stated that this task depends on the typical laboratory volume mix for each service, and any blanket categorization cannot be justified.

Response: We continue to believe that the clinical labor task “Order, restock, and distribute specimen containers with requisition forms” is an indirect PE, as it is not allocated to any individual service. We have defined direct PE inputs as clinical labor, medical supplies, or medical equipment that are individually allocable to a particular patient for a particular service. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69629). Therefore, whether a particular cost is fixed or variable does not determine whether it is a direct PE input under the methodology. We have removed the recommended 0.5 minutes of time for clinical labor task “Order, restock, and distribute specimen containers with requisition forms” from all seven of these procedures. However, we have maintained 0.5 minutes of time for clinical labor task “Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician” from the previous recommendations for CPT codes 88160, 88161, and 88162, and added this 0.5 minutes to the other four codes in the family to conform with the other codes in the family.

Comment: Several commenters disagreed that there is a lack of clarity and possibility for confusion within the cytopathology smears, screening and interpretation family. These commenters stated that in CPT code 88160, the slide is received in the laboratory typically as a spray-fixed and air-dried slide that has not been stained. The slide is then stained in the laboratory with the appropriate stain per fixation prior to review and interpretation. For CPT code 88161, the laboratory must first put the patient material on the slide (that is, prepare the slide) then stain it in the laboratory with the appropriate stain per fixation prior to review and interpretation. Both codes therefore include staining, review and interpretation in the laboratory. Commenters did not agree that there was any provider confusion concerning these specialized,

low volume codes, and stressed that these codes did not need to be added to the potentially misvalued code list.

Response: We appreciate the additional information clarifying the nature of the work that takes place during these two procedures.

Comment: The same commenters did not agree with the refinement to the time for clinical labor task “Stain air dried slides with modified Wright stain” from 5 minutes to 0 minutes for CPT code 88160 and from 5 minutes to 3 minutes for CPT code 88161.

Commenters explained that for CPT code 88160, the slides are received in the laboratory typically as spray-fixed and air-dried slides that have not been stained. They must be stained prior to review and interpretation. For CPT code 88161, the laboratory must put the patient material on the slide, followed by staining for review and interpretation. Both codes therefore include staining, review and interpretation in the laboratory.

Response: We appreciate the submission of this additional information regarding the staining of slides in these procedures. After consideration of comments received and based on the submission of this additional information, we agree that there should be time for allocated for clinical labor task “Stain air dried slides with modified Wright stain” in CPT code 88160. We later received additional recommendations from the RUC that suggested a time of 2 minutes for the clinical labor task. We are therefore accepting the time for clinical labor task “Stain air dried slides with modified Wright stain” at the value of 2 minutes in the most recent set of RUC recommendations for all seven procedures; we believe that 2 minutes is an accurate standard for this clinical labor task.

Comment: One commenter disagreed with the CMS refinement to the clinical labor task “Prepare automated stainer with solutions and load microscopic slides.” The commenter stated that 4 minutes were recommended for this task, which applied specifically to these particular CPT codes based on the typical laboratory and efficiency assumptions.

Response: We agree with the commenter that 4 minutes is an accurate value for this clinical labor task, but note that we refined the value to 4 minutes during our initial review.

Comment: A commenter recommended that CMS refine the equipment time of the solvent recycling system to 2 minutes. The commenter expressed the opinion that the use of this equipment is not dependent on clinical labor time.

Response: We continue to believe that the solvent recycling system is an indirect PE cost used across numerous services and not individually allocated to particular procedures. We have removed the clinical labor time associated with the solvent recycling system from all seven codes.

In addition, we have removed the time associated with clinical labor task “Recycle xylene from stainer” from all of the codes for similar reasons. We also noticed what appeared to be an error in the amount of non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) assigned to CPT codes 88108 and 88112. The recommended value of these supplies was a quantity of 0.2, which we believe was intended to be a quantity of 2. We are therefore refining the value of these supplies to 2 for CPT codes 88108 and 88112. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88104, 88106, 88108, 88160, 88161, and 88162 with the exception of the refinements to the clinical labor, supplies, and equipment described above.

g. Flow Cytometry, Cell Cycle or DNA Analysis (CPT Code 88182)

We refined many of the clinical labor activities in this procedure to align with the typical times included for other recently reviewed pathology codes. We requested additional information regarding the use of the desktop computer with monitor (ED021) since the RUC recommendation did not specify how it is used.

Comment: One commenter disagreed with the eight refinements that CMS made to the clinical labor time for CPT code 88182, and with the rationale of using clinical labor standards

for pathology activities in general. The commenter stated that the time for these clinical labor tasks varies for each CPT code, and the RUC-recommended times only reflect the time associated with each particular CPT code. The times associated with pathology clinical labor activities vary by typical laboratory-specific efficiencies, such as batch size. The commenter stated that it was inappropriate for CMS to establish standard clinical labor times for these clinical labor activities, and urged CMS to accept the RUC recommendation for these inputs.

Response: We refer the reader to section II.A. of this final rule for our discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. We continue to believe that our refinements to clinical labor time ensure the most accurate values for these activities, based on a comparison with other pathology codes that share these same clinical labor activities.

Comment: Several commenters provided additional information concerning the use of the desktop computer with monitor. These commenters explained that CPT code 88182 is performed using ploidy analysis, by comparing the tumor curve to normal cells. These analyses are performed using a dedicated desktop computer with a monitor, which is located in the same room and is dedicated to the patient for each use.

Response: We appreciate the submission of additional information regarding the use of the desktop computer with monitor. After consideration of comments received, we believe that the use of this equipment item is typical during this service and will retain this equipment item for CPT code 88182. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Code 88182.

h.. Flow Cytometry, Cytoplasmic Cell Surface (CPT Codes 88184 and 88185)

We refined many of the clinical labor activities in these procedures to align with the times typically included in other recently reviewed pathology codes. We also requested 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.

Comment: Many commenters disagreed with the decrease in direct PE inputs for these codes. Commenters emphasized that the CMS proposal for these codes reflected reductions in the PE RVUs of 38 percent to CPT code 88184 and 69 percent to CPT code 88185. Commenters stated that these reductions are unreasonable and could jeopardize patient access to care. Several commenters requested that these codes be re-reviewed by the RUC process because certain inputs were not considered in the original RUC deliberations.

Response: We agree with the commenters that there were major changes to the direct PE inputs for these two procedures. We note that almost all of the change in direct PE inputs resulted from RUC recommendations. With the exception of the equipment time for the dye sublimation color photo printer and the clinical labor activities that we refined to bring into accordance with pathology standards, we used the RUC-recommended values to develop proposed PE inputs for these codes and we believe that they provide the most accurate valuation for these services.

Comment: Several commenters indicated that the pathology specialties inadvertently left an equipment item out of their recommendation, Flow Cytometry Analytics Software. The commenters stated that this software is typically used for both CPT codes 88184 and 88185, and recommended adding 10 minutes of equipment time to CPT code 88184 along with 2 minutes of equipment time for CPT code 88185.

Response: Equipment time for flow cytometry analytics software is not currently included in CPT codes 88184 and 88185, and equipment time for this software was not included in the RUC recommendation for these procedures. We believe that if there are new direct PE inputs for these procedures, the commenter should publicly nominate CPT codes 88184 and 88185 for further review through the potentially misvalued code initiative.

Comment: Multiple commenters disagreed with the CMS decision to refine the time for clinical labor task “Other Clinical Activity: Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer.” The commenters requested adding 10 minutes to this clinical labor task for CPT code 88184 and 2 minutes for CPT code 88185. This additional time would reflect the Cytotechnician’s time spent using the Cytometry Analytics Software to analyze the data generated from the service on a designated desktop computer, w-monitor (ED021). The commenters also requested adding these additional minutes to the equipment time for the desktop computer.

Response: We continue to believe that 7 minutes is the most accurate time for this clinical labor task for CPT code 88184 based on a comparison with CPT code 88182, which is another flow cytometry code in the same family where we included the recommended 7 minutes of time for the same clinical labor task. Since we do not believe that this clinical labor time would be typical, we also do not believe that an additional 10 minutes would be typical for use of the desktop computer with monitor. We continue to believe that the recommended 20 minutes of equipment time for the desktop computer with monitor, which is shared by CPT code 88182, is the most accurate value for CPT code 88184.

Comment: Several commenters stated that the pathology specialties inadvertently miscalculated the amount of supply item “antibody, flow cytometry” (SL186) that are necessary for CPT codes 88184 and 88185. The commenters recommended a revised supply quantity of 1.6 for both codes instead of the quantity of 1 included in the RUC recommendation.

Response: CPT codes 88184 and 88185 currently use 1 unit of supply SL186, and the recommendation for these procedures also indicated that 1 unit of supply SL186 is typical. We continue to agree with the RUC recommendation that 1 unit of supply SL186 is the most accurate amount for these procedures. If the commenter believes that these codes are potentially misvalued, then we suggest the submission of a public comment following the publication of the

CY2016 final rule with comment period to nominate CPT codes 88184 and 88185 as a potentially misvalued code that could facilitate development of new recommended values.

Comment: A commenter explained that the equipment time for the dye sublimation color photo printer (ED031) is independent of clinical labor time. The commenter suggested that CMS should therefore accept the RUC recommendation of 5 minutes of equipment time for CPT code 88184 and 2 minutes for CPT code 88185, instead of the CMS refinement of 1 minute chosen to reflect the clinical labor time assigned to printing in each procedure.

Response: We appreciate the commenter bringing this issue to our attention. Although we agree with the general principle that equipment time for printers may not align with clinical labor time assigned to printing, we do not agree that 5 minutes of equipment time would be the most accurate value for the dye sublimation color photo printer assigned to CPT code 88184. However, we did notice that we inadvertently set the equipment time of this printer to 1 minute, when it should have been 2 minutes to align with the time for clinical labor task “Print out histograms.” After consideration of comments received, we are refining the equipment time of the dye sublimation color photo printer to 2 minutes for CPT code 88184, and maintaining an equipment time of 1 minute for the dye sublimation color photo printer for CPT code 88185.

Comment: Several commenters disagreed with the CMS refinement to the time for clinical labor task “Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation.” The commenters stated that entering this information takes additional time, that these are extremely important tasks that require technical skill, and assigning zero minutes to this clinical labor task is illogical for a service like flow cytometry.

Response: We have not recognized the laboratory information system as an equipment item that can be allocated to an individual service. We continue to believe that this is a form of

indirect PE, and therefore we do not recognize the laboratory information system as a direct PE input, as we do not believe this task is typically performed by clinical labor for each service.

Comment: One commenter stated that CMS should accept the RUC recommendation of 5 minutes of clinical labor for “Print out histograms, assemble materials with paperwork to pathologists, review histograms and gating with pathologists.” The commenter stated that it is not reasonable to expect a cytotechnologist to print out histograms, assemble the documents and deliver them to a pathologist, and review the histograms with a pathologist, all in the span of 2 minutes. The commenter stated that a technologist would not be able to produce a high quality product and ensure its accuracy in the clinical labor time assigned to this task by CMS.

Response: We believe that in order to maintain relativity, it is important to apply standards to ensure consistency in the time for the same clinical labor task among similar procedures. In refining the time for this clinical labor task, we examined procedures that included the same task, such CPT code 88182, which include 2 minutes for this task. Therefore, we continue to believe that 2 minutes is the appropriate value for this clinical labor task.

Comment: A commenter requested that CMS maintain the current quantity of supply item “lysing reagent” (SL089). The commenter indicated that there are increased supply costs associated with the newer, more automated flow cytometers, such as additional costs for tandem conjugates and other fluorochromes. Although the commenter agreed that the new technology may require less lysing reagent supplies, they urged CMS to maintain the current supply quantity of SL089.

Response: We believe that the increasing use of new technology reduces the need for the same quantity of lysing reagent used in the past for these procedures. Since the commenter did not provide a rationale for us to maintain the current quantity for supply item SL089 relative to the actual use of that quantity in furnishing the service, we continue to agree that the RUC-

recommended quantities of 5 ml for CPT code 88184 and 2 ml for CPT code 88185 are the most accurate amounts of lysing reagent typically required for these procedures.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 88184 and 88185, with the additional refinements to equipment time discussed above.

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

We proposed to remove the time for clinical labor task “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 proposed to maintain the recommended 4 minutes for this clinical labor task for CPT code 88323, since it does require slide preparation.

We proposed to refine the time for clinical labor task “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 standard time for clinical labor task “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 allocation of indirect PE under our established methodology.

We proposed to refine the time for clinical labor 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” from 7 minutes to 5 minutes. Based on the description of this task, we

indicated that we believe that this task would typically take 5 minutes to be performed by the Lab Technician.

We proposed to remove supply item “eosin solution” (SL063) from CPT code 88323. We do not agree that this supply would typically be used in this procedure, since the eosin solution is redundant when used together with supply item “hematoxylin stain supply” (SL135). We also refined the quantity of SL135 from 32 to 8 for CPT code 88323, to be consistent with its use in related procedures.

We proposed 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 proposed to refine the labor, supplies, and equipment inputs to align with the inputs recommended for CPT code 88321, which also does not include the preparation of slides.

Comment: One commenter disagreed with the CMS refinements and urged CMS to accept the RUC recommendations. The commenter stated that the clinical labor task “Accession specimen/prepare for examination” is actually far more time consuming for outside cases than accessioning inside cases, due to the need to individually identify and enter each slide and block. The commenter disagreed with the CMS proposal to remove this clinical labor time for CPT codes 88321 and 88325.

Response: According to the code descriptors, there is no slide preparation taking place in CPT codes 88321 and 88325. These services consist of the consultation and review of specimens prepared by another practitioner. We continue to believe that accession of specimens would not be typical for these procedures, and we therefore maintain that time should not be allocated for this clinical labor task. In addition, any clinical labor required for preparation of the referred slides is already included in the descriptions for other clinical labor tasks included for these codes, such as:

- Register the patient in the information system, including all demographic and billing information. In addition to standard accessioning, enter contributing physician name and address, number of slides and the outside case number, etc., into the laboratory information system. Print labels for slides, and affix labels to slides.

- Print label for outside block and affix to block.
- List and label all accompanying material (imaging on a disk, portion of chart, etc.)

Comment: The commenter also disagreed with the CMS refinement to the time for clinical labor task “Register the patient in the information system, including all demographic and billing information.” The commenter stated that these tasks are performed in addition to accessioning the specimen and preparing for examination.

Response: We continue to believe that the typical time for the clinical labor task “accession of specimen” is 4 minutes, based on comparison to other pathology services. We refined the time for this clinical labor task to 5 minutes based on our belief that the additional tasks involving label preparation would typically take 1 minute. We also continue to believe that the additional recommended time for CPT codes 88321, 88323, and 88325 likely reflects administrative tasks that are appropriately accounted for in the indirect PE methodology.

Comment: A commenter disagreed with the proposal to remove the time for clinical labor tasks “Assemble and deliver slides with paperwork to pathologists” and “Clean equipment while performing service” for CPT code 88323. The commenter stated that the assembling of slides in this task was a separate task from the clinical labor associated with preparation of materials associated with the non-frozen section processing of the specimen. The commenter also stated that for the typical laboratory setting, specific equipment must be cleaned and maintained immediately after use.

Response: We continue to believe that these are duplicative clinical labor activities. CPT code 88323 already includes time for clinical labor task “Complete workload recording

logs. Collate slides and paperwork. Deliver to pathologist” and “Clean room/equipment following procedure.” We do not believe that there it would be typical to assemble slides or clean the room twice.

Comment: The commenter disagreed with the removal of the eosin solution (SL063) from CPT code 88323. The commenter stated that the eosin solution would be used for the hematoxylin stain (SL135), and elimination of this supply item would likely compromise patient care. The commenter also indicated that 32 ml of the hematoxylin stain is typical for these services in the typical laboratory setting.

Response: We appreciate the additional information regarding this supply and its importance for staining in this procedure. After consideration of comments received, we believe that this is the most accurate type of eosin supply for use in this type of slide staining because it is most similar to the eosin supply previously used in CPT code 88323. Therefore, we are replacing supply SL063 with supply SL201 (stain, eosin) and restoring a quantity of 8 ml for CPT code 88323. We are also refining our proposed quantity of 8 ml of the hematoxylin stain to 16 ml for CPT code 88323. The current supply inputs for CPT code 88323 have twice the amount of hematoxylin stain compared to eosin, 4.8 compared to 2.4, and we are maintaining the same 2:1 ratio.

Comment: The commenter disagreed with the removal of time for many clinical labor tasks in CPT code 88325, such as “Dispose of remaining specimens”, “Prepare, pack and transport specimens and records for in-house storage and external storage”, and several other activities related to slide preparation. The commenter objected to the standardization of clinical labor tasks across differing pathology codes, and stated that these are necessary and integral tasks for this service that cannot be eliminated without compromising standards of care.

Response: As the code descriptor indicates for CPT code 88325, we continue to believe that there is no slide preparation taking place in this procedure. Therefore, we do not believe that

clinical labor tasks related to the preparation of slides or the disposal of hazardous waste materials would typically be performed.

Comment: The commenter also disagreed with the CMS decision to remove supplies and equipment unassociated with slide preparation from CPT code 88325. The commenter wrote to indicate that when hematoxylin and eosin (H&E) slides are prepared from referred blocks, all technical services are performed. The commenter urged that the recommended supplies and equipment be restored to CPT code 88325.

Response: We do not agree that referred materials require the same clinical labor, supplies, and equipment as materials prepared locally. The vignette for CPT code 88325 states that the pathologist performing the service is receiving prepared slides from another laboratory; therefore, we do not believe that the use of these supplies and equipment associated with slide preparation would be typical for the second pathologist performing this consultation.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88321, 88323, and 88325, with the additional refinement to the eosin stain and hematoxylin stain supplies discussed above in CPT code 88323.

j. Pathology Consultation during Surgery (CPT Codes 88329, 88331, 88332, 88333, and 88334)

We refined many of the clinical labor activities in these procedures to align with the typical times included in recently reviewed pathology codes, in particular the clinical labor times for CPT code 88305. We also removed supply item “H&E stain kit supply” (SL231) and replaced it with supply item “H&E frozen section stain supply” (SL134) and refined the quantity of the microscope slides (SL122) for CPT codes 88333 and 88334.

Comment: A commenter disagreed with the CMS refinement of these clinical labor activities. The commenter stated that clinical labor times should not be standardized for pathology services, and that although standards may be used as a starting point, the work for pathology codes varies depending on the pathology task that is being done.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. For these pathology consultation codes, we have refined the clinical labor times to bring them into accordance with other similar codes, in particular CPT code 88305. For example, we do not believe that the time for clinical labor task “Assist pathologist with gross specimen examination” for a consultation procedure (as in CPT code 88331) should require more clinical labor time than the identical clinical labor task in a tissue biopsy procedure (as in CPT code 88305).

Comment: The same commenter stated that 3 minutes of time for clinical labor task “Clean room/equipment following procedure” is the standard for surgical procedures, and the same clinical labor time should be applied to pathology procedures.

Response: We do not believe that clinical labor times for surgical procedures are typically applicable to pathology procedures. We believe that it is more accurate to compare clinical labor times for pathology procedures to other pathology procedures that utilize the same clinical labor tasks. In the case of the clinical labor for “Clean room/equipment following procedure”, we continue to believe that 1 minute is the standard time for these services, based on a comparison to other recently reviewed pathology codes.

Comment: The commenter stated that the H&E stain supply kit removed by CMS is needed to perform the procedure for CPT codes 88331 and 88332, as the kit is needed to prepare the slides (that is, xylene, alcohol, bluing agent, etc). The commenter also stated that the preamble text in the CY 2016 PFS proposed rule did not state anything specific about this substitution, and that CMS must supply a better rationale for this proposed change.

Response: We appreciate the opportunity to clarify our position regarding the replacement of the H&E stain supply kit with an H&E frozen section stain. We noticed that these procedures had previously been performed using 1 H&E frozen section stain, which was

removed by the RUC in favor of a quantity of 0.1 of supply item “H&E stain supply kit”.

Because the RUC recommendation did not explain why the use of an H&E stain supply kit would be typical, we believed that it would be more accurate to maintain the quantity of 1 for supply item “H&E frozen section stain” as is currently included in these codes. We believe that this maintains relativity with other codes in the family, and maintains consistency with other related pathology procedures.

Comment: A different commenter disagreed with the CMS decision to remove the time for clinical labor task “Prepare room. Filter and replenish stains and supplies.” The commenter stated that this dedicated room must be prepared for the next immediate consultation after each service; stains must be filtered and changed, while cryostats and chucks must be cleaned. The commenter requested the restoration of the RUC recommended clinical labor time.

Response: We continue to believe that the preparation in this clinical labor task is duplicative with the clinical labor assigned for “Clean room/equipment following procedure.” We also continue to believe that the labor involved in replenishing stains and supplies is not allocated to an individual service, and therefore comprises an indirect PE.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88329, 88331, 88332, 88333, and 88334.

k. Morphometric Analysis (CPT Code 88355)

We refined many of the clinical labor activities in these procedures to align with the standard times used by other recently reviewed pathology codes, in particular the clinical labor times for CPT code 88305. We also removed the equipment time for the ultradeep freezer (EP046), as we believe that items used for storage such as freezers are more accurately classified as indirect PE.

Comment: One commenter disagreed with the CMS removal of the equipment time for the ultradeep freezer. The commenter stated that the use of the ultradeep freezer is specific to

CPT code 88355. While other specimens may be stored in the same freezer, freezer space is unavailable for other specimens or items during storage. Freezer space is therefore a variable direct expense dependent upon patient specimen caseloads, and should be considered a direct expense for pathology services.

Response: As we stated in the CY 2016 PFS proposed rule (80FR 41699), we do not believe that minutes should be allocated to items such as freezers since the storage of any particular specimen in a freezer for any given length of time would be unlikely to make the freezer unavailable for storing other specimens. We continue to believe that the ultradeep freezer is most accurately classified as an indirect PE since freezers can be used for many specimens at once. We refer readers to our discussion of direct PE inputs earlier in this section.

Comment: The same commenter objected to the CMS refinements to standard pathology times for clinical labor tasks “Assemble and deliver slides with paperwork to pathologist”, “Clean room/equipment following procedure,” and “Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit.” The commenter indicated their disagreement with these refinements and the standardization of pathology clinical labor tasks more generally, as the time for these tasks varies for each unique service.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. For this morphometric analysis of the skeletal muscle procedure, we have refined the clinical labor times to bring them into accordance with other similar procedures.

Comment: The commenter disagreed with the CMS refinement to the time for clinical labor task “Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.” The commenter explained that nerves and muscle typically arrive in the

laboratory on saline soaked gauze held in a clamp, and the tissue requires specialized knowledge to further prepare and process it. The commenter stressed that the specimen preparation for these services is vastly different than for routine surgical pathology specimens where large numbers of specimen containers are prepared at one time, and therefore the typical batch size for this type of specimen would be one, necessitating the increased time.

Response: We appreciate the additional description of the clinical labor tasks taking place in CPT code 88355 provided by the commenter. Based on this presentation of further clinical information and after consideration of comments, we believe that additional time for clinical labor task “Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.” is appropriate. We note that the original RUC recommendation included 9 minutes for this clinical labor task. However, this clinical labor task is related to clinical labor task “Accession specimen/prepare for examination”. To avoid duplicative preparation labor, we have assigned an additional 4.5 minutes relative to our proposal, for a total of 5 minutes, of time for clinical labor task “Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician” for CPT code 88355.

Comment: The commenter requested that CMS adopt the RUC-recommended time of 4 minutes for clinical labor task for “Prepare, pack and transport specimens and records for storage.” The commenter explained that these specimens are quite unique and require special care and handling and the time allocated to this task is typically longer than other pathology specimens.

Response: We appreciate the commenter submission of additional information regarding this clinical labor task. After consideration of comments received, we believe that it would be more accurate to increase the time for this clinical labor task to 3 minutes for CPT code 88355, to reflect the additional preparation taking place over the typical storage of specimens in other pathology procedures.

Comment: The commenter disagreed with the CMS decision to remove the recommended time for clinical labor task “Prepare specimen for -70 degree storage.” The commenter stated that this task was not on the table of standard times for clinical labor tasks associated with pathology services included in the CY 2016 PFS proposed rule, and this specimen preparation task is unique to CPT code 88355.

Response: We believe that the resource costs associated with storage preparation are accurately accounted for under the minutes assigned to the clinical labor tasks “Prepare, pack and transport specimens and records for storage” for CPT code 88355. We believe that the clinical labor associated with preparation for -70 degree storage would be duplicative of this clinical labor task. We have also added additional time for clinical labor task “slide storage preparation” under the clinical labor task “Prepare, pack and transport specimens and records for storage” to reflect the extra storage requirements of this procedure.

Comment: The commenter also disagreed with the CMS decision to refine the time for clinical labor task “Assist pathologist with gross examination.” The commenter wrote that specialty knowledge is required to further process the tissue. The tag of nerve or muscle outside the clamp must be carefully trimmed by hand with the trimmings going to formalin containers. Clinical labor staff is needed to collaborate with the pathologist often to prepare the specimen and process the specimen. Tissue must be examined and, if too thick, must be further trimmed to allow penetration by glutaraldehyde. The properly trimmed, clamped tissue can then be transferred to a glutaraldehyde container, which is then transferred to a refrigerator for at least 24 hours when it can then be processed with further consultation with the pathologist.

Response: We appreciate the submission of additional clinical information regarding the clinical labor utilized in the performance of CPT code 88355. However, we do not agree that all of this labor would take place during the “Assist pathologist with gross examination” task. We believe that the information provided by the commenter describes several other steps in the

procedure, such as “Measure specimen and fix on muscle/nerve clamp” and “Process specimen for slide preparation”, each task having its own respective clinical labor time. In order to avoid the potential for duplicative clinical labor, we are maintaining the CMS refinement to 3 minutes for clinical labor task for “Assist pathologist with gross examination” for CPT code 88355.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 88355, with the additional clinical labor refinements discussed above.

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

We refined many of the clinical labor activities in these procedures to align with the typical times included in recently reviewed pathology codes. We also proposed 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 proposed to reclassify these two pieces of equipment as a single item with a price of \$150,000, which will use equipment code EP112. CPT codes 88360 and 88361 have been valued using this new price. The equipment minutes remain unchanged.

The RUC recommendation for CPT codes 88360 and 88361 included an invoice for supply item “Antibody Estrogen Receptor monoclonal” (SL493). The submitted invoice had a price of \$694.70 per box of 50, or \$13.89 per test. We sought publicly 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 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 proposed to establish a new supply code for “Antibody Estrogen Receptor monoclonal” and price that item at \$3.19 each. We welcomed comments from stakeholders regarding this supply item.

Comment: Several commenters disagreed with the CMS refinements to the time for clinical labor task “Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer”, “Verify results and complete work load recording logs”, and “Recycle xylene from tissue processor and stainer.” The commenters stated that entering patient data requires far longer than the 1 minute proposed by CMS, and that removing the time for clinical labor tasks related to verifying results and recycling xylene could result in laboratory disaccreditation or errors that are harmful to patients.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. We continue to believe it is most accurate to allocate zero minutes of time for the task “Verify results and complete work load recording logs”, and “Recycle xylene from tissue processor and stainer”, as we believe that these are indirect PE tasks not allocated to any individual service.

Comment: One commenter provided a list of eight additional clinical labor activities for CPT code 88360 and one additional clinical labor task for CPT code 88361. The commenter suggested that CMS should consider adding these tasks, which were not included in the RUC recommendations, into its labor estimates for the two procedures.

Response: We appreciate the suggestion from the commenter of additional tasks that can aid in the performance of IHC special stains. We believe that the tasks associated with furnishing particular PFS services could be described and categorized in various ways. We believe that particular tasks should be considered in the context of comprehensive review that allows for an assessment of overall number of minutes involved in furnishing the service. If the commenter examines the list of clinical labor tasks used by the RUC to develop recommendations for these services and finds that many tasks are missing, then we believe that the commenter may want to

consider submitting the codes through the public nomination process of the misvalued code initiative to improve the accuracy of the valuations.

Comment: Another commenter disagreed with CMS' refinement to the equipment time of the compound microscope (EP024). The commenter stated that this refinement was not discussed in the preamble text, and that the time involves 35 minutes of work time plus 1 minute of clinical labor time, as described in the RUC recommendation. The commenter asked for CMS to accept the RUC recommended equipment time of 36 minutes.

Response: We note that we did not fully explain our rationale for the refinement of equipment time for the compound microscope equipment time. We observed that the description of the intraservice work for the physician includes many tasks that do not use the microscope. As a result, we do not believe that use of the compound microscope would be typical for the entire intraservice period. We continue to believe that the most accurate equipment time for the compound microscope is 25 minutes: 24 minutes for the work time (66 percent of 35 minutes) plus 1 minute for the technician.

Comment: Many commenters disagreed with the CMS proposal to price supply item "monoclonal antibody estrogen receptor" (SL493) at \$3.19. Commenters stated that this was substantially lower than the submitted invoice of \$13.89; CMS instead referenced the Estrogen Receptor Antibody (h-151) [DyLight 405] for its price of \$3.19. Commenters stated that this supply is for research use only, and that it is not approved for use in humans or in clinical diagnosis. According to the commenters, this item is not an alternate reagent for CPT codes 88360 and 88361, and would not be used for these services.

Response: We appreciate all of the additional information provided by the commenter. The only pricing information that we received for SL493 was an invoice that included a handwritten price over redacted information. We were unable to verify the accuracy of this invoice. In order to price SL493 appropriately, we believe that we need additional information. We will use

the publicly available price of \$3.19 as a proxy value pending the submission of additional pricing information. We welcome the submission of updated pricing information regarding SL493 through valid invoices from commenters and other stakeholders.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88360 and 88361.

m. Nerve Teasing Preparations (CPT Code 88362)

We proposed to refine the recommended time for clinical labor task “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 noted that the 5 minutes includes 3 minutes for assisting the pathologist with the gross specimen examination (as listed in Table 6 of the proposed rule (80 FR 41698) and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen.

Comment: Several commenters disagreed with the CMS decision to refine the time for clinical labor task “Assist pathologist with gross specimen examination” from 10 minutes to 5 minutes. The commenters stated that the pathologist must work together with clinical labor staff during the gross specimen work, and the clinical labor could not be performed in 5 minutes due to the number of specimens involved.

Response: We continue to believe that the 5 minutes for this clinical labor task included 3 minutes for assisting the pathologist with the gross specimen examination and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen. We also continue to believe that this is the most accurate value for this clinical labor task in the absence of additional data supporting an increase in the time for this clinical labor task.

Comment: These commenters also expressed their disagreement with the CMS removal of the recommended time for clinical labor task “Consult with pathologist regarding

representation needed, block selection and appropriate technique.” Commenters stated that clinical labor staff must collaborate with the pathologist in the preservice time, and the unique technical protocols required for nerve teasing pathology services requires the clinical labor staff to have a complete understanding of what is necessary for each individual specimen case. Commenters emphasized that nerve teasing pathology services cannot be batched as they are complex, low volume unusual studies requiring special handling, preparation, and storage.

Response: We continue to believe that the clinical labor described in this clinical labor task constitutes basic knowledge for a practicing Histotechnologist. We noted that this clinical labor task appears to be unique to CPT code 88362, and does not appear in other pathology services. We do not believe it maintains relativity to include increasingly specialized clinical labor tasks that are not included in similar procedures. We also do not believe that it would be typical for the Histotechnologist to require this kind of extensive consultation with the pathologist before performing each individual procedure, since the technician would have prior knowledge of what he or she will be doing.

Comment: One commenter disagreed with the CMS refinements to clinical labor tasks associated with slide preparation. For the clinical labor tasks “Assemble and deliver cedar mounted slides with paperwork to pathologists”, “Assemble other light microscopy slides, epon nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation”, and “Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste”, the commenter indicated that there are less batch size efficiencies with these specimens compared to other typical surgical pathology services, and the recommendation for extra clinical labor time reflected the need for careful handling of materials.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. The proposed refinement to 0.5 minutes for

these clinical labor tasks reflects the time typically included for slide preparation established across many different pathology procedures.

Comment: The same commenter disagreed with the CMS refinement to the time for clinical labor tasks “Preparation: labeling of blocks and containers and document location and processor used” and “Accession specimen and prepare for examination.” The commenter stated that although they agreed with the reduction in time, they disagreed with the refinement rationale and the standardization of pathology clinical labor tasks, as the time for each task varies for each CPT code.

Response: We appreciate that the commenter’s support for our proposal to reduce the clinical labor for these activities. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes assuming similar batch sizes, and we appreciate further comments as we work to establish clinical labor standards across pathology services.

Comment: The commenter did not agree with the CMS refinement to the time for clinical labor task “Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician.” The commenter explained that nerves and muscle typically arrive in the laboratory on saline soaked gauze for this procedure. Specialty knowledge is required to further prepare and process the tissue, and as a result the specimen preparation for CPT code 88362 is different from routine surgical pathology specimens where large numbers of specimen containers are prepared at one time. The commenter stated that the typical batch size for this type of specimen would be one, which necessitates the increased time.

Response: We appreciate the additional description of the clinical labor taking place in CPT code 88362 provided by the commenter. Based on this presentation of further clinical information, and in order to maintain consistency with our refinements to CPT code 88355, we believe that additional clinical labor time is appropriate. Since this is the same clinical labor task

taking place in CPT code 88355, we will also assign 5 minutes for “Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician” for CPT code 88362 using the same rationale as described for 88355.

Comment: The commenter also disagreed with the CMS refinements to the time for clinical labor task “Prepare, pack and transport specimens and records for in-house storage and external storage” and “Prepare, pack and transport cedar oiled glass slides and records for in-house special storage.” The commenter stressed that the specimens used in these labor tasks were unique to CPT code 88362, and therefore they cannot be standardized as part of a wider set of clinical labor activities for the field of pathology. However, the commenter did agree that the clinical labor task “Prepare, pack and transport specimens and records for in-house storage and external storage” would typically take 1 minute, although the typical time in the commenter’s specialized laboratory would be higher.

Response: We appreciate the commenter’s support for our proposal to refine the time for clinical labor task “Prepare, pack and transport specimens and records for in-house storage and external storage”. We continue to believe that this and other pathology clinical labor tasks more generally, can be standardized across different services. We do not believe that there should be time allocated for clinical labor task “Prepare, pack and transport cedar oiled glass slides and records for in-house special storage” for this procedure, since there is already time for clinical labor tasks related to preparing, packing, and transportation of materials.

Comment: The commenter also did not agree with the CMS removal of the recommended time for clinical labor task “Storage remaining specimen. (Osmicated nerve strands, potential for additional teased specimens).” The commenter stated that this clinical labor task was not listed anywhere in the proposed rule to explain why CMS believes this is a standard clinical labor task. This storage clinical labor task is unique to CPT code 88362 and its removal could potentially compromise patient care.

Response: We appreciate this opportunity to clarify our rationale regarding the refinement to this clinical labor task. We believe that the clinical labor described in this clinical labor task is duplicative of the clinical labor described in the task “Prepare, pack and transport specimens and records for in-house storage and external storage.” We do not believe that the use of three different clinical labor activities for storage of specimens would be typical for CPT code 88362.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 88362, with the additional clinical labor refinements discussed above.

n. Nasopharyngoscopy with Endoscope (CPT Code 92511)

We proposed to remove the endosheath (SD070) from this procedure, because we indicated that 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 stated we believed it would be appropriate to remove all of the clinical labor and equipment time currently assigned to cleaning the scope. We sought public comment regarding the proper use of the endosheath supply and the clinical labor associated with scope cleaning.

Comment: Several commenters agreed that the endosheath is not typically used for CPT code 92511 and was inadvertently included from past direct PE inputs for the service. The commenters stated that after removing the endosheath, it was appropriate to retain all the clinical labor and equipment time assigned to cleaning the scope. In addition, in order to clean the equipment and to be consistent with other codes in the family, commenters requested adding four supplies to the code associated with scope cleaning, which were excluded previously because the endosheath was retained.

Response: We appreciate the additional clarification from the commenters regarding the use of supply item “endosheath” for this procedure. After consideration of comments received,

we agree that it is appropriate to retain the clinical labor and equipment time assigned to cleaning the scope, as well as include the additional requested cleaning supplies. Based on this additional information, we are refining the direct PE inputs to include the following supply items: 2 endoscope cleaning brushes (SM010), 4 oz. of enzymatic detergent (SM015), 4 oz. of glutaraldehyde 3.4% (SM018), and 1 glutaraldehyde test strip (SM019).

Comment: One commenter disagreed with the CMS decision to remove the recommended surgical masks, impervious staff gowns, and non-sterile drape sheet from the procedure. The commenter stated that these supplies were necessary, with one mask and gown needed for the physician and one mask and gown needed for the staff, since the procedure produces a lot of secretion transmission. Therefore, these were not duplicative supplies.

Response: We appreciate the additional clarification regarding the use of these supplies. After consideration of comments received, we are restoring these supplies and adding 2 surgical masks (SB033), 2 impervious staff gowns (SB027), and 1 non-sterile sheet drape (SB006) to CPT code 92511 in the non-facility setting.

After consideration of comments received, we are finalizing the direct PE inputs for CPT code 92511, with the additional supply refinements described above.

o. EEG Extended Monitoring (CPT Codes 95812 and 95813)

We refined several of the clinical labor times for CPT codes 95812 and 95813 to align them with our proposed standards, including refining the time for clinical labor task “Assist physician in performing procedure” to align with the intraservice time of each procedure. We also removed the service period time for clinical labor task “Provide pre-service education/obtain consent” to avoid duplicative clinical labor with the same task in the preservice period, and refined several of the equipment times to align with the standard equipment times for non-highly technical equipment.

Comment: Some commenters did not agree with the CMS refinement of the time for clinical labor task “Assist physician in performing procedure.” The commenters stated that the practitioner reads the patient record subsequently without the technologist present, and that the intraservice work time is not temporally equivalent with the tech’s assist physician clinical labor time. The line “Assist physician in performing procedure” was used as a surrogate data entry line for where to place the technologist’s service in performing the testing, and it was not meant to be taken literally. The commenter therefore requested that CMS adopt the RUC-recommended time for both procedures.

Response: The RUC recommendation for these procedures explicitly stated that CPT code 95812 requires 50 minutes of time for clinical labor task “EEG recording”, and CPT code 95813 requires 80 minutes of clinical labor time for the same clinical labor task. We do not believe that existing clinical labor tasks should be used as data entry surrogates for other tasks, and we do not believe that clinical labor time should be allocated to tasks that are not described in the submitted recommendations. We continue to believe that this represents the clinical labor time which would be spent assisting the physician in performing the procedure.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 95812 and 95813.

p. Testing of Autonomic Nervous System Function (CPT Code 95923)

We proposed to reduce the quantity of supply item “iontophoresis electrode kit” (SA014) from 4 to 3. According to the description of this code, the procedure typically uses 2-4 electrodes, and we indicated that we therefore believe that a supply quantity of 3 would better reflect the typical case. We requested 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 recommended that the code descriptor be referred to CPT for further clarification.

Comment: Several commenters pointed out that CMS incorrectly labeled this section of the CY 2016 PFS proposed rule under the heading of “Needle Electromyography” with associated CPT codes 95863, 95864, 95869, and 95870. Commenters inferred that CMS intended to reference CPT code 95923 instead of the needle electromyography procedures.

Response: The commenters are correct, and we agree that we included the wrong heading for this part of the CY 2016 PFS proposed rule (80 FR 41781). We apologize for any confusion caused by this error.

Comment: The commenters also explained that the use of 4 iontophoresis electrode kits would be typical for CPT code 95923. According to the commenters, several experts in the field of autonomic testing confirmed that when providing this service they always, without exception, used at least 4 sites of iontophoresis: forearm, proximal leg, distal leg, and foot. The commenters therefore maintained that 4 units of the iontophoresis electrode kit would be the appropriate quantity.

Response: We appreciate the submission of this additional clinical information regarding the use of the iontophoresis electrodes. After consideration of comments received, we are increasing the quantity of the iontophoresis electrode kit (SA014) to 4 for CPT code 95923 in line with the recommended value.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Code 95923, with the additional refinement to SA014 discussed above.

q. Central Motor Evoked Study (CPT Codes 95928 and 95929)

We refined portions of the clinical labor time for CPT codes 95928 and 95929 as duplicative with other tasks, and refined the time for clinical labor task “Assist physician in performing procedure” to align with the intraservice work duration. We also removed a minimum multi-specialty visit pack (SA048) from CPT code 95928 due to the fact that it is

typically billed with a same-day E/M service, and we refined some of the equipment times for both procedures to conform to the standard equipment formulas.

Comment: One commenter disagreed with the CMS decision to refine the time for clinical labor task “Assist physician in performing procedure” to align with the intraservice work time. This commenter stated that the technologist sets up the service without the physician present, after which the physician enters the room for the main portion of the testing. Afterwards, the physician leaves the room and the technologist completes the last portion of the procedure without the physician present. The commenter indicated that the time for clinical labor task “Assist physician in performing procedure” and the physician intraservice work time were not temporally equivalent, and that this clinical labor task was only used as a surrogate data entry line for where to place the technologist’s service in performing the testing, not meant to be taken literally.

Response: The RUC recommendation for CPT codes 95928 and 95929 states that the technologist will “Assist physician in conducting the test.” As a result, we do not believe that the clinical labor assigned to “Assist physician in performing procedure” was merely a surrogate data entry line that was not meant to be taken literally. We do not agree that existing clinical labor tasks should be used as data entry surrogates for other tasks, and we do not believe that clinical labor time should be allocated to tasks that are not described in the submitted recommendations. We continue to believe that this clinical labor task should align with the intraservice work time, and we are maintaining durations of 40 minutes for CPT code 95928 and 95929.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 95928 and 95929.

r. Blink Reflex Test (CPT Code 95933)

We added 2 minutes of time for clinical labor task “Prepare room, equipment, supplies” to CPT code 95933 and refined the time for clinical labor task “Clean room/equipment by physician staff” to 3 minutes, in both cases conforming to the established standards for these clinical labor tasks.

Comment: One commenter indicated that the CY 2016 PFS proposed rule summary showed a net reduction in PE relative value units for CPT code 95933, from a 2015 PE RVU of 1.75 to a proposed 2016 PE RVU of 1.50. The commenter disagreed with this reduction and stated that they were unable identify the source for the proposed reductions.

Response: To clarify the proposed change in PE for CPT code 95933, we note that we believe this reduction is due to two changes in the recommended values. We accepted the RUC recommendation to reduce the time for clinical labor task “Assist physician in cleaning area, relaxing patient. Take notes from physician” from 30 minutes to 25 minutes. We also accepted the RUC recommendation to reduce the quantity of supply item “electrode skin prep gel (NuPrep)” (SJ022) from 100 ml to 10 ml. These two reductions likely account for the reduction in PE RVUs.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 95933.

8. CY 2015 Interim Final Codes

In this section, we discuss each code for which we received a comment on the CY 2015 interim final work RVU or work time during the comment period for the CY 2015 final rule or for which we are modifying the CY 2015 interim final work RVU, work time or procedure status indicator for CY 2016. If a code in Table 15 is not discussed in this section, we did not receive any comments on that code or received only comment(s) in support of the CY 2015 interim final status; for those, we are finalizing the interim final work RVU and time without modification for CY 2016.

A comprehensive list of all interim final values for which public comments were sought in the comment period for the CY 2015 PFS final rule is contained in Addendum C to the CY 2015 PFS final rule with comment period. We note that the values for some codes with interim final values were addressed in the CY 2016 PFS proposed rule (see: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>), and therefore, are addressed in section II.H. of this final rule with comment period. A comprehensive list of all CY 2016 RVUs is in Addendum B. All Addenda to the PFS final rule with comment period are available on the CMS Web site under downloads at <http://www.cms.gov/physicianfeesched/PFSFederalRegulationNotices.html/>. The time values and direct PE inputs for all codes are listed files called “CY 2016 PFS Work Time,” and “CY 2016 Direct PE Inputs,” available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at <http://www.cms.gov/physicianfeesched/downloads/>.

TABLE 13: CY 2016 Actions on Codes with CY 2015 Interim Final RVUs

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	1.10	1.10	Finalize
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting	0.89	0.89	Finalize
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting	1.00	1.00	Finalize
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting	1.10	1.10	Finalize
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation	7.13	7.13	Finalize
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1-3 ribs	10.79	10.79	Finalize
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 ribs	13.00	13.00	Finalize
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs	17.61	17.61	Finalize
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic	8.15	8.15	Finalize
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral	7.58	7.58	Finalize
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)	4.00	4.00	Finalize
22513	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;	8.90	8.90	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
	thoracic			
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	8.24	8.24	Finalize
22515	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; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)	4.00	4.00	Finalize
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	24.05	24.05	Finalize
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)	8.40	8.40	Finalize
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	9.03	9.03	See II.J.5.a
29200	Strapping; thorax	0.39	0.39	Finalize
29240	Strapping; shoulder (eg, Velpeau)	0.39	0.39	Finalize
29260	Strapping; elbow or wrist	0.39	0.39	Finalize
29280	Strapping; hand or finger	0.39	0.39	Finalize
29520	Strapping; hip	0.39	0.39	Finalize
29530	Strapping; knee	0.39	0.39	Finalize
31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])	1.40		Deleted
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode	4.92	4.92	Finalize
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator	5.87	5.87	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator	5.84	5.84	Finalize
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator	6.07	6.07	Finalize
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator	6.15	6.15	Finalize
33223	Relocation of skin pocket for implantable defibrillator	6.55	6.55	Finalize
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)	9.04	9.04	Finalize
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)	8.33	8.33	Finalize
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead	6.05	6.05	Finalize
33241	Removal of implantable defibrillator pulse generator only	3.29	3.29	Finalize
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy	23.57	23.57	Finalize
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	13.99	13.99	Finalize
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber	15.17	15.17	Finalize
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system	6.06	6.06	Finalize
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system	6.33	6.33	Finalize
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed	9.10	9.10	Finalize
33271	Insertion of subcutaneous implantable defibrillator electrode	7.50	7.50	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
33272	Removal of subcutaneous implantable defibrillator electrode	5.42	5.42	Finalize
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	6.50	6.50	Finalize
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	32.25	32.25	Finalize
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)	7.93	7.93	Finalize
33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous	6.00	6.00	Finalize
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial	6.63	6.63	Finalize
33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial	4.60	4.60	Finalize
33951	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	8.15	8.15	Finalize
33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	8.15	8.15	Finalize
33953	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	9.11	9.11	Finalize
33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	9.11	9.11	Finalize
33955	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	16.00	16.00	Finalize
33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6	16.00	16.00	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
	years and older			
33957	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	3.51	3.51	Finalize
33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	3.51	3.51	Finalize
33959	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed)	4.47	4.47	Finalize
33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)	4.47	4.47	Finalize
33963	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed)	9.00	9.00	Finalize
33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)	9.50	9.50	Finalize
33965	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age	3.51	3.51	Finalize
33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older	4.50	4.50	Finalize
33969	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth	5.22	5.22	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
	through 5 years of age			
33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	5.46	5.46	Finalize
33985	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	9.89	9.89	Finalize
33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older	10.00	10.00	Finalize
33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)	4.04	4.04	Finalize
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	15.00	15.00	Finalize
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	9.50	9.50	Finalize
34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time	B	B	Finalize
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)	C	C	Finalize
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)	C	C	Finalize
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	C	C	Finalize
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated	5.30	5.30	See II.J.5.a
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)	2.65	2.65	See II.J.5.a
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated	5.30	5.30	See II.J.5.a
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)	2.65	2.65	See II.J.5.a
36818	Arteriovenous anastomosis, open; by upper arm cephalic vein transposition	12.39	12.39	Finalize
36819	Arteriovenous anastomosis, open; by upper arm basilic vein transposition	13.29	13.29	Finalize
36820	Arteriovenous anastomosis, open; by forearm vein transposition	13.07	13.07	Finalize
36821	Arteriovenous anastomosis, open; direct, any site (eg, Cimino type) (separate procedure)	11.90	11.90	Finalize
36825	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft	14.17	14.17	Finalize
36830	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (eg, biological collagen, thermoplastic graft)	12.03	12.03	Finalize
36831	Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure)	11.00	11.00	Finalize

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36832	Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	13.50	13.50	Finalize
36833	Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	14.50	14.50	Finalize
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation	15.00	15.00	Finalize
43180	Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed	9.03	9.03	Finalize
45399	Unlisted procedure, colon	I	C	Finalize
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	9.13	9.13	Finalize
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	4.50	4.50	Finalize
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	1.20	1.20	Finalize
55840	Prostatectomy, retropubic radical, with or without nerve sparing;	21.36	21.36	Finalize
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	21.36	21.36	Finalize
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	25.18	25.18	Finalize
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;	12.29	12.29	Finalize
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	14.16	14.16	Finalize
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	14.39	14.39	Finalize
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	15.60	15.60	Finalize
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;	13.36	13.36	Finalize
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	15.00	15.00	Finalize
58572	Laparoscopy, surgical, with total	17.71	17.71	Finalize

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	hysterectomy, for uterus greater than 250 g;			
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	20.79	20.79	Finalize
62284	Injection procedure for myelography and/or computed tomography, lumbar (other than C1-C2 and posterior fossa)	1.54	1.54	Finalize
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical	2.29	2.29	Finalize
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic	2.29	2.29	Finalize
62304	Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral	2.25	2.25	Finalize
62305	Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)	2.35	2.35	Finalize
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic	1.91	1.91	Finalize
62311	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.54	1.54	Finalize
62318	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic	2.04	2.04	Finalize
62319	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.87	1.87	Finalize
64486	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)	1.27	1.27	Finalize

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64487	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)	1.48	1.48	Finalize
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	1.60	1.60	Finalize
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	1.80	1.80	Finalize
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	5.44	5.44	Finalize
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft	14.00	14.00	Finalize
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft	15.00	15.00	Finalize
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft	9.58	9.58	Finalize
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft	10.58	10.58	Finalize
67036	Vitrectomy, mechanical, pars plana approach;	12.13	12.13	Finalize
67039	Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation	13.20	13.20	Finalize
67040	Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation	14.50	14.50	Finalize
67041	Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (eg, macular pucker)	16.33	16.33	Finalize
67042	Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (eg, for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil)	16.33	16.33	Finalize
67043	Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (eg, choroidal neovascularization), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil) and laser photocoagulation	17.40	17.40	Finalize
67255	Scleral reinforcement (separate procedure); with graft	8.38	8.38	Finalize
70486	Computed tomography, maxillofacial area; without contrast material	0.85	0.85	See II.J.5.a
70487	Computed tomography, maxillofacial area; with contrast material(s)	1.13	1.13	See II.J.5.a
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast	1.27	1.27	See II.J.5.a

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	material(s) and further sections			
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	Finalize
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	Finalize
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.82	1.82	Finalize
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.81	1.81	Finalize
72240	Myelography, cervical, radiological supervision and interpretation	0.91	0.91	Finalize
72255	Myelography, thoracic, radiological supervision and interpretation	0.91	0.91	Finalize
72265	Myelography, lumbosacral, radiological supervision and interpretation	0.83	0.83	Finalize
72270	Myelography, 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation	1.33	1.33	Finalize
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	2.20	2.20	Finalize
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.82	1.82	Finalize
74230	Swallowing function, with cineradiography/videoradiography	0.53	0.53	Finalize
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete	0.73	0.73	Finalize
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited	0.68	0.68	Finalize
76700	Ultrasound, abdominal, real time with image documentation; complete	0.81	0.81	Finalize
76705	Ultrasound, abdominal, real time with image documentation; limited (eg, single organ, quadrant, follow-up)	0.59	0.59	Finalize
76770	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; complete	0.74	0.74	Finalize
76775	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation;	0.58	0.58	Finalize

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	limited			
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete	0.69	0.69	Finalize
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (eg, for follicles)	0.50	0.50	Finalize
76930	Ultrasonic guidance for pericardiocentesis, imaging supervision and interpretation	0.67	0.67	Finalize
76932	Ultrasonic guidance for endomyocardial biopsy, imaging supervision and interpretation	0.85	0.67	Finalize
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation	0.67	0.67	Finalize
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation	0.38	0.38	Finalize
77055	Mammography; unilateral	0.7	0.70	Finalize
77056	Mammography; bilateral	0.87	0.87	Finalize
77057	Screening mammography, bilateral (2-view film study of each breast)	0.7	0.70	Finalize
77061	Digital breast tomosynthesis; unilateral	I	I	Finalize
77062	Digital breast tomosynthesis; bilateral	I	I	Finalize
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	0.60	0.60	Finalize
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)	0.20	0.20	Finalize
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment	0.30	0.30	Finalize
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)	0.17	0.17	Finalize
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician	0.62	0.62	See II.J.5.a
77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)	1.40	1.40	See II.J.5.a
77307	Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)	2.90	2.90	See II.J.5.a

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77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)	1.40	1.40	Finalize
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)	1.83	1.83	Finalize
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)	2.90	2.90	Finalize
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	0.53	0.53	See II.I.5.d
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	0.70	0.70	Finalize
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure	0.77	0.77	Finalize
88348	Electron microscopy, diagnostic	1.51	1.51	Finalize
88356	Morphometric analysis; nerve	2.80	2.80	Finalize
88364	In situ hybridization (eg, FISH), per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	0.67	0.67	See II.I.5.d
88365	In situ hybridization (eg, FISH), per specimen; initial single probe stain procedure	0.88	0.88	Finalize
88366	In situ hybridization (eg, FISH), per specimen; each multiplex probe stain procedure	1.24	1.24	Finalize
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	0.67	0.67	See II.I.5.d
88373	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	0.43	0.43	Finalize
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure	0.93	0.93	See II.I.5.d
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain	1.40	1.40	Finalize

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	procedure			
88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	1.14	1.14	See II.J.5.a
88381	Microdissection (ie, sample preparation of microscopically identified target); manual	0.53	0.53	See II.J.5.a
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report	0.30	0.27	See II.J.5.a
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	0.17	0.17	Finalize
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording	1.50	1.50	Finalize
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording	0.40	0.40	Finalize
92542	Positional nystagmus test, minimum of 4 positions, with recording	0.48	0.48	Finalize
92543	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests), with recording	0.10		Deleted
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording	0.27	0.27	Finalize
92545	Oscillating tracking test, with recording	0.25	0.25	Finalize
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system	0.85	0.85	Finalize
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system	0.74	0.74	Finalize
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable	0.85	0.85	Finalize

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	defibrillator system			
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system	1.15	1.15	Finalize
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system	1.25	1.25	Finalize
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system	0.45	0.45	Finalize
93289	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements	0.92	0.92	Finalize
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report	2.55	2.55	Finalize
93313	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only	0.51	0.51	Finalize
93314	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only	2.10	2.10	Finalize
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	2.94	2.94	Finalize

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93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only	0.85	0.85	Finalize
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only	2.09	2.09	Finalize
93318	Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	2.40	2.40	Finalize
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete	0.38	0.38	Finalize
93321	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)	0.15	0.15	Finalize
93325	Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	0.07	0.07	Finalize
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	4.66	4.66	Finalize
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	3.29	3.29	Finalize
93880	Duplex scan of extracranial arteries; complete bilateral study	0.80	0.80	Finalize
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.50	0.50	Finalize
93886	Transcranial Doppler study of the intracranial arteries; complete study	0.91	0.91	Finalize

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93888	Transcranial Doppler study of the intracranial arteries; limited study	0.50	0.50	Finalize
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	N	N	Finalize
93925	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study	0.80	0.80	Finalize
93926	Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study	0.50	0.50	Finalize
93930	Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study	0.80	0.80	Finalize
93931	Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study	0.50	0.50	Finalize
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study	0.70	0.70	Finalize
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study	0.45	0.45	Finalize
93975	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study	1.16	1.16	Finalize
93976	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study	0.80	0.80	Finalize
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study	0.80	0.80	Finalize
93979	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study	0.50	0.50	Finalize
93990	Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)	0.50	0.50	Finalize
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	0.78	0.78	Finalize

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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 1 hour	0.80	0.80	Finalize
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)	0.49		Deleted
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	0.55	0.55	Finalize
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	0.60	0.60	Finalize
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	C	C	Finalize
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for	C	C	Finalize

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	ongoing care, per session; total wound(s) surface area greater than 50 square centimeters			
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.35	0.35	Finalize
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session	2.11	2.11	Finalize
99184	Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude EEG, supervision of controlled hypothermia, and assessment of patient tolerance of cooling	4.50	4.50	Finalize
99188	Application of topical fluoride varnish by a physician or other qualified health care professional	N	N	Finalize
99487	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	B	B	Finalize
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.	0.61	0.61	Finalize
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	0.00	0.00	Finalize
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206)	0.60	0.60	Finalize
G0389	Ultrasound b-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening	0.58	0.58	Finalize
G0473	Face-to-face behavioral counseling for obesity,	0.23	0.23	Finalize

HCPCS Code	Long Descriptor	CY 2015 Interim Final Work RVU	CY 2016 Work RVU	CY 2016 Action
	group (2-10), 30 minutes			

a. Specific Issues for Codes with CY 2015 Interim Final Values

(1) Ablation Therapy (CPT Code 20983)

In CY 2015 we established the RUC-recommended work RVU for CPT code 20983 and made minor refinements to the RUC-recommended direct PE inputs.

Comment: A commenter stated that the total clinical labor times in the direct PE input database are inconsistent with the RUC-recommended values. The commenter mentioned that some of the service period activity time was assigned to the total post-service clinical labor time.

Response: We reviewed the direct PE input database and confirmed the time for clinical labor task “Assist Physician” was missing for labor type L046A. We will restore the missing labor time as we intended to establish as interim final the RUC recommendation for the clinical labor times without refinement.

(2) Automatic Fixation of Rib Fracture (CPT Codes 21811, 21812, and 21813)

For CY 2015, the CPT Editorial Panel deleted CPT code 21810 (Treatment of rib fracture requiring external fixation) and replaced it with CPT codes 21811, 21812, and 21813 to address internal fixation of rib fracture. As described in the CY 2015 PFS final rule with comment period, the RUC recommended that we value these procedures with 90-day global periods. We indicated that we believed it would be more appropriate to value these procedures with 0-day global periods. We valued each of these services by subtracting the work RVU related to postoperative care from the total work RVU. We also refined the RUC-recommended time by subtracting the time associated with the postoperative visits, and removed direct PE inputs associated with the postoperative visits.

In the CY 2015 PFS final rule with comment period, we considered whether certain pre-

service clinical labor tasks would typically be performed given that these procedures are frequently furnished on an emergency basis. We reviewed other emergency procedures valued under the PFS to determine whether pre-service clinical labor activities were typically included in the PE worksheets and found that the recommendations for these procedures were inconsistent. Therefore, in the CY 2015 PFS final rule with comment period, we did not remove the time allocated for certain clinical labor activities, but sought public comment on this issue.

Comment: One commenter expressed concerns with the methodology employed by CMS. The commenter stated that CMS staff had attended the RUC meeting where these codes were reviewed and were aware that a building block methodology (BBM) was not used to build the work RVUs for these codes. Therefore, the commenter suggested it was incorrect for CMS to use a reverse BBM to calculate a new value.

Response: We are committed to establishing the most accurate valuation possible for each procedure. In this case, we examined the results of the reverse BBM and determined that it was the most appropriate approach to value these services. Due to the emergency nature of these procedures, we believe that they are more accurately valued using a 0-day global period.

Comment: Another commenter reminded CMS that the specialty societies surveyed these three codes based on a 90-day global period and that CMS had ample opportunity to inform the RUC and the specialties of an impending change in the global assignment prior to the development of recommended RVUs.

Response: We understand that the specialties surveyed the codes under the assumption that they would be valued with a 90-day global period, prior to our determination that these services would be more accurately valued as 0-day globals due to their emergency nature. We believe that in the case of these emergent services, it may not be typical for the individual performing the initial procedure to be responsible for providing the follow-up care. Therefore, we believe that the 0-day global period to more accurately reflect the care furnished. This is

precisely why it was necessary for us to account for the change in global period when establishing interim final work RVUs for the codes. To do so, we employed a reverse BBM to establish separate work RVUs for the individual procedure in each case. As we have previously stated, we believe that the best way to improve the valuation of codes that describe multiple services over long periods of time (for example, 90 days) is to develop discrete values for the component services. We agree that survey results are likely to be most useful when there is consistency between the global period as surveyed and the global period in the final valuation of the code. However, because we did not have such survey data in this case, we used another established methodology to develop a potential work RVUs. In this case, we believe that the reverse building block methodology establishes the most accurate value for this group of codes. Although the RUC recommends global periods for individual services and often consults with CMS staff regarding the typical global periods for such services, we believe that it is appropriate to establish global period for particular codes through rulemaking. If stakeholders are concerned about the final values for services surveyed based on a presumed global period that is not ultimately applied to the individual code, then we encourage stakeholders to consider nominating such codes as potentially misvalued through the public nomination process.

Comment: One commenter suggested that CMS did not provide reference codes with 0-day global periods to support the new interim final work RVUs. The commenter disagreed with the work RVUs established by CMS and suggested that all three of the codes in question were undervalued. The commenter provided information about other codes with 0-day global periods that had similar work time. The commenter urged CMS to reinstate the 90-day global period and accept the RUC recommendations for work RVUs, similar to other trauma codes.

Response: After reviewing the codes provided by the commenter, we believe that the values of other existing codes support our valuation of these procedures. For CPT code 21811, we note that CPT code 93650 (Intracardiac catheter ablation of atrioventricular node function)

shares the same intraservice time of 120 minutes and has a higher total time (240 minutes compared to 220 minutes for CPT code 21811), but a lower work RVU of 10.49. We believe that the work RVU assigned to CPT code 21811 fits well within the work RVUs for the group of codes that have 0-day global periods and 120 intraservice minutes. For CPT code 21812, we note that 92997 (Percutaneous transluminal pulmonary artery balloon angioplasty), which has 5 additional minutes of intraservice time (155 minutes compared to 150 minutes for 21812) and a higher total time (275 minutes compared to 250 minutes for 21812), has a lower work RVU of 11.98. We believe that our valuation of CPT code 21812 maintains relativity within this group of 0-day global codes with times of approximately 150 intraservice minutes.

For CPT code 21813, we agree with the commenter that there is a lack of 0-day global codes with comparable intraservice times. We also agree with the commenter's suggestion that CPT codes 93654 and 93656 provide the best references available. These codes share an intraservice time of 240 minutes compared to the 210 minutes of intraservice time for CPT code 21813. However, we disagree with the commenter that CPT code 21813 is undervalued based on a comparison of these intraservice times. Applying the ratio between the 210 minutes for CPT code 21813 and the 240 minutes for the reference CPT code 93654 (0.875) to the work RVU of 20.00 for CPT code 93654, results in a work RVU of 17.50. This is similar to our valuation for CPT code 21813 of 17.61. We believe that this intraservice time ratio further supports our valuation of CPT code 21813, which maintains relativity with similar 0-day global codes. After consideration of comments received, we are finalizing the interim final work RVUs for CPT codes 21811, 21812, and 21813 for CY 2016.

(3) Percutaneous Vertebroplasty and Augmentation (CPT Codes 22510, 22511, 22512, 22513, 22514, and 22515)

In CY 2015, we established the RUC-recommended work RVUs as interim final for all of the codes in this family except CPT code 22511 because we did not agree with its RUC-

recommended crosswalk. To value this code, we took the difference between the work RVUs for the predecessor codes for CPT codes 22510 and 22511, CPT codes 22520 (Percutaneous vertebroplasty (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; thoracic)) and 22521 (Percutaneous vertebroplasty (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; thoracic; lumbar)) and applied that to the work RVU we established for CPT code 22510. We believed that increment established the appropriate rank order in the family, and thus, assigned an interim final work RVU of 7.58 for CPT code 22511.

Comment: A commenter disagreed with the methodology CMS used for valuing CPT code 22511 because they believed CMS' approach was arbitrary and invalidated the RUC process of using new survey data. The commenter urged CMS to accept the RUC-recommended work RVU of 8.05 for this code.

Another commenter requested that CMS reconsider the RVUs for these codes. The commenter believed that, due to the bundling of these imaging codes for CY 2015, additional PE costs were added to the service. The commenter expressed concerns that practitioners might find it infeasible to furnish these services in the non-facility setting if payment continues to be based on the interim final values we adopted for CY 2015.

Additionally, several commenters alerted CMS to missing clinical labor times for "assist physician" for all of the codes in this family. Some commenters also stated that clinical labor time was missing for the post-operative visit in CPT codes 22510, 22511, 22513, and 22514.

Response: Unlike other codes in this family for which the RUC-recommended work RVU was based on the 25th percentile in the survey, the RUC established its recommended work RVU for CPT code 22511 by crosswalking the service to CPT code 39400 (Mediastinoscopy, includes biopsy(ies), when performed), which has a work RVU of 8.05. Because the level of work performed by a practitioner in the two services differs, we continue to believe that this

crosswalk is inaccurate. We maintain that a more accurate comparison is found in the difference between the work RVUs for the predecessor codes for CPT codes 22510 and 22511 and that applying this differential leads to appropriate valuation.

We agree with the commenters that there were inconsistencies in the clinical labor times for these codes as entered in our direct PE database. We direct the reader to section II.B. of this final rule with comment period for a discussion of these clinical labor input inconsistencies.

Therefore, we are finalizing our CY 2015 work valuation for CPT codes 22510, 22511, 22512, 22513, 22514, and 22515.

(4) Total Disc Arthroplasty (CPT code 22856)

In the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVU for CPT code 22856, consistent with the RUC recommendation.

Comment: One commenter suggested that CPT code 22856 has been undervalued since 2009. The commenter believed CMS should value this service relative to several other codes that together comprise standard anterior cervical discectomy and fusion which the commenter believes is appropriately valued. The commenter stated that a higher valuation would be consistent with higher procedure operating room time included for CPT code 22856 in six clinical trials.

Response: We appreciate the submission of this additional information about the current practice of cervical disc replacement from the commenter. However, for the purpose of valuation, we typically compare a procedure against a broad range of other procedures across the PFS to help maintain relativity, rather than a single related procedure. In addition to intraservice operating time, other resource costs are included in the work RVU, such as the clinical intensity of the procedure and the time and intensity of the pre- and post-work, including post-operative visits.

After consideration of comments received, we are finalizing the CY 2015 interim final

work RVU for CY 2016 without modification, consistent with the RUC recommendation.

(5) Sacroiliac Joint Fusion (CPT code 27279)

In the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVU for CPT code 27279, consistent with the RUC recommendation.

Comment: Several commenters stated that the RUC survey data were not reliable because the reference service (CPT code 62287, Percutaneous discectomy) with a work RVU of 9.03 is not comparable. One of the commenters, a professional association, recommended a work RVU of 14.36 based upon its own survey or a work RVU of 13.18 based on a comparison with CPT code 63030 (Low back disk surgery). This commenter requested that CMS refer CPT code 27279 to the multispecialty refinement panel.

Response: CPT code 27279 was referred to the CY 2015 Multi-Specialty Refinement Panel per the commenter's request. The outcome of the refinement panel was a median of 9.03 work RVUs. After consideration of the comments and the results of the refinement panel, we are finalizing our interim final work RVU of 9.03 for CPT code 27279.

(6) Subcutaneous Implantable Defibrillator Procedures (CPT Codes 33270, 33271, 33272, 33273, 93260, 93261 and 93644)

For CY 2015, the CPT Editorial Panel added the word "implantable" to the descriptors for several codes in this family and created several new codes (CPT codes 33270, 33271, 33272, 33273, 93260, 93261, and 93644). We established as interim final the RUC-recommended work RVUs for all of the codes in this family except CPT code 93644. The RUC-recommended times for CPT code 93644 included an intraservice time of 20 minutes and a total time of 84 minutes. We disagreed with the RUC-recommended direct crosswalk for CPT code 93644 because the code that serves as the source for the crosswalk had greater intraservice time (29 minutes) and total time (115 minutes). We believed that a crosswalk to CPT code 32551 was more accurate since the intraservice time for CPT code 32551 was 20 minutes, total time was 83 minutes, and

intensity was comparable. Therefore, we established a CY 2015 interim final work RVU of 3.29 for CPT code 93644.

Comment: Two commenters expressed disappointment that CMS did not accept the RUC recommendation for CPT code 93644. The commenters disagreed with the decision to crosswalk the work RVU for CPT code 93644 from CPT code 32551 because they believed that the services were not similar in nature. Commenters suggested that CMS accept the RUC recommendation with a crosswalk from CPT code 15002, due to a similar intraservice time. The commenters also requested that CPT code 93644 be referred to the multispecialty refinement panel.

Response: We continue to believe that crosswalking the value for CPT code 93644 from CPT code 32551 is the best way to value this service due to the codes' similar intraservice and total times and similar intensity. We believe that the difference in time values for the RUC-recommended crosswalk is too great to serve as a direct crosswalk for overall work. We did not receive any new clinical information needed for referral of this code to the multispecialty refinement panel. Therefore, we are finalizing our CY 2015 valuation.

(7) Fenestrated Endovascular Repair (FEVAR) Endograft Planning (CPT Codes 34839-34848)

For CY 2015, we examined several FEVAR codes. CPT code 34839 was created to report the planning that occurs prior to the work included in the global period for a FEVAR. We accepted the RUC recommendation for all of the codes in this family except CPT code 34839. We believed the planning that occurs prior to the work was included in the global period for FEVAR and should be bundled with the underlying service. We did not believe bundling was inappropriate in this case. Accordingly, we assigned a PFS procedure status indicator of B (Bundled Code) to CPT code 34839.

Comment: One commenter requested that CMS issue coding guidance regarding with which codes the FEVAR co-surgeon modifier can be used.

Response: We appreciate the commenter's feedback. We will take this comment into consideration in developing guidance for use of the co-surgeon modifier.

(8) Endovenous Ablation Therapy (CPT Codes 36475-36479)

For CY 2015, we examined several endovenous ablation therapy codes and used the RUC-recommended work RVUs to establish interim final work RVUs. We made minor refinements to the RUC recommended direct PE inputs to establish interim final direct PE inputs for this family of codes.

Comment: A commenter requested that CMS review the difference in PE inputs between CPT codes 36475 and 36478. The commenter stated that they believed CPT code 36478 was missing supplies which are commonly used in the procedure, and that this difference in reimbursement could only be explained by errors in the supply and staff inputs. The commenter also provided clinical information suggesting that the laser technique of endovenous ablation therapy described in CPT code 36478 is more effective than the radiofrequency treatment described in CPT code 36475.

Response: We thank the commenter for bringing this issue to our attention. We agree that there are errors in the direct PE database regarding these two codes. After consideration of comments received, we are making the following refinements. For CPT code 36475, we are adding one unit of supply item "needle, spinal 18-26g" (SC028) and one unit of supply item "syringe 20 ml" (SC053). For CPT code 36478, we are adding 5 minutes of clinical labor time of staff type L037D for "Apply multi-layer comprehensive dressing" and adding 3 minutes of clinical labor time of the same type for "Check dressings & wounds." We are also removing 2 minutes of clinical labor time of staff type L054A for "Patient clinical information and questionnaire reviewed by technologist", as this time was inadvertently included in the direct PE database. This results in identical clinical labor inputs for the two procedures, as the commenter correctly pointed out should be the case.

With regards to the commenter's feedback regarding the supplies allocated to CPT codes 36475 and 36478, we reviewed the direct PE inputs as recommended by the RUC and agree that they represent the typical inputs used in furnishing these procedures.

Comment: One commenter disagreed with all of the PE refinements made in this family. The commenter stated that 30 minutes was typical recovery time for input code EF019 (stretcher chair) and that 32 minutes is the time the room is unavailable to other patients for input codes EL015 (room, ultrasound, general), EQ215 (radiofrequency generator (vascular)), and EQ160 (laser, endovascular ablation (ELVS)). The commenter also stated that additional images are inherent to the add-on codes which justify the extra minute in input code L054A (vascular technologist). Another commenter expressed support for CMS' acceptance of the RUC-recommended RVUs and times for these services.

Response: In establishing interim final times for the direct equipment inputs, we followed our standard methodologies that resulted in the allocated equipment times for EL015, EL215, and EQ160 for these codes in the direct PE input database. We believe that adherence to these standard methodologies maintains relativity within the development of PE RVUs and is likely to reflect the typical case. We disagree with commenters regarding the equipment times for EL015, EL215, and EQ160. However, we agree additional images are inherent in the add-on codes, which supports the additional minute of clinical labor time. Therefore, we are finalizing the interim final values for these services, with the exception of the refinements to the clinical labor, supplies, and equipment described above.

(9) Cryoablation of Liver Tumor (CPT Code 47383)

For CY 2015, we proposed the RUC-recommended work RVU of 9.13 for CPT code 47383 and made several refinements to the recommended clinical labor and equipment times.

Comment: A commenter stated that the clinical labor time associated with the 99212 postoperative visit did not appear in the CMS direct PE public use files.

Response: We appreciate the assistance from the commenter in bringing this issue to our attention. We have corrected this error in the CMS direct PE public use files; we note that this issue was limited to the public use files and had no impact on the calculation of PE RVUs. For further information, please see the Identification of Database Errors in section II.H. of this final rule with comment period.

After consideration of comments received, we are finalizing the CY 2015 interim final work RVU and direct PE inputs as proposed for CPT code 47383.

(10) Transprostatic Implant Procedures (TIP) (CPT Codes 52441 and 52442)

In CY 2015, we established the RUC-recommended work RVUs and direct PE inputs as interim final for CPT codes 52441 and 52442.

Comment: One commenter agreed with the list and total cost of direct PE supplies established by CMS.

Response: We appreciate the commenter's supportive comments. We are finalizing our CY 2015 valuation for CPT codes 52441 and 52442.

(11) Laparoscopic Hysterectomy (CPT codes 58541, 58542, 58543, 58544, 58570, 58571, 58572, and 58573)

In the CY 2015 final rule with comment period, we established as interim final the RUC-recommended work RVUs and direct PE inputs for these codes.

Comment: Two commenters requested that these codes be sent to the multispecialty refinement panel prior to finalizing their work RVUs for CY 2016. Commenters stated that gynecologic oncologists were not offered the chance to participate in the RUC surveys for these procedures. As a result, the survey results did not reflect the typical patients that receive these procedures from practitioners of that specialty, who have complex medical needs with co-morbid conditions and complications. Commenters also indicated that the Food and Drug Administration (FDA) recently discouraged the use of morcellation during these procedures,

which increases the amount of time it takes to perform the procedure and remove the fibroids prior to removing the uterus. The commenters stated that these changes need to be taken into account with new data prior to finalizing these work RVUs.

Response: We received and granted a request for multispecialty refinement panel review based on the presentation of new clinical information. However, the specialty groups making the original request later chose not to present these procedures at the 2015 Multi-Specialty Refinement Panel. After consideration of comments received and the lack of review by the multispecialty refinement panel, we are finalizing the CY 2015 interim final work RVUs for CPT codes 58541, 58542, 58543, 58544, 58570, 58571, 58572, and 58573 for CY 2016.

(12) Myelography (CPT Codes 62284, 62302, 62303, 62304, 62305, 72240, 72255, 72265, and 72270)

In the CY 2015 PFS final rule with comment period, we accepted the RUC-recommended work RVU for these nine codes on an interim final basis. We made refinements to the clinical labor and equipment time for the non-radiological codes in the family.

Comment: A commenter stated that the RUC recommended only a single staff type for the myelography codes, with clinical labor L041B for the radiological codes and L037D for the non-radiological ones. The commenter stated that they did not believe it would be typical to have two staff types involved in the procedure, and suggest allocating all minutes for the non-radiological codes to L037D.

Response: We agree with the commenter that assigning all of the clinical labor to a single staff type for each of the two types of procedure in the myelography family would be more typical for these services. Therefore we are changing the clinical labor type from L041B to L037D for the clinical labor activities “Availability of prior images confirmed”, “Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist” and “Assist physician in performing procedure” for CPT codes

62302, 62303, 62304, and 62305. This ensures a single staff type for each of the nine codes in this family.

After consideration of comments received, we are finalizing these codes as proposed, with the change in clinical staff type detailed above.

(13) Maxillofacial Computed Tomography (CT) (CPT Codes 70486, 70487 and 70488)

In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work RVU to establish an interim final work RVU of 0.85 for CPT code 70486 (Computed tomography, maxillofacial area; without contrast material). The RUC arrived at this value by crosswalking CPT code 70486 to CPT code 70460 (Computed tomography, head or brain; with contrast material(s)), which is the equivalent code in the head and brain CT family. To maintain rank order within and across CT families, we crosswalked the work RVU for CPT code 70487 (Computed tomography, maxillofacial area; with contrast material(s)) from CPT code 70460 (Computed tomography, head or brain; with contrast material(s)). We also crosswalked the work RVU for CPT code 70488 (Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections) from CPT code 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections). Therefore, we established interim final work RVUs of 1.13 for CPT code 70487 and 1.27 for CPT code 70488.

Comment: For CPT codes 70487 and 70488, commenters suggested that the CMS crosswalks did not accurately reflect the intensity of maxillofacial CT. Commenters suggested that CPT codes 70487 and 70488 require a thinner CT slice technique than the CMS crosswalks of CPT codes 70460 and 70470, and that the volume of images to be interpreted is greater. Commenters suggested that maxillofacial CTs were instrumental in imaging potentially dangerous conduits, which could be damaged due to maxillofacial disease.

Response: We continue to believe that since the lowest of the brain CT code family was

an accurate crosswalk for CPT code 70486, the other two codes in the brain CT family are also accurate crosswalks for CPT codes 70487 and 70488. The procedures are similar in terms of both intraservice time and complexity of the anatomical region. While commenters requested that these codes be addressed by the multispecialty refinement panel, the request did not include information reflecting new clinical evidence, and therefore, did not meet the established criteria for review by the multispecialty refinement panel.

Comment: For CPT codes 70487 and 70488, commenters requested 3 minutes for the clinical labor task “Provide pre-service education and obtain consent.”

Response: Upon review of the task “provide pre-service education and obtain consent,” we agree with commenters that 3 minutes is an accurate estimate for the amount of time required to discuss the risks involved in these procedures. Three minutes also maintains consistency within the code family. Therefore, we are including 3 minutes for “provide pre-service education and obtain consent in the direct PE input database.

(14) Abdominal Ultrasound (CPT Codes 76700, 76705, 76770, 76775, 76856, and 76857)

For CY 2015, we used the RUC-recommended work RVUs and PE inputs to establish interim final values for six codes in the abdominal ultrasound family.

Comment: Commenters noted that CPT codes 76700 and 76705 were missing from the direct PE input database.

Response: We appreciate the commenters’ attention to detail and we have included these codes in the updated direct PE input database.

(15) Breast Ultrasound (CPT Codes 76641 and 76642)

For CY 2015, the CPT Editorial Panel replaced CPT code 76645 (Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation) with two codes: CPT codes 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) and 76642 (Ultrasound, breast, unilateral, real time with image

documentation, including axilla when performed; limited). We used the RUC-recommended work RVUs of 0.73 and 0.68 to establish interim final work RVUs for CPT codes 76641 and 76642, respectively.

Comment: A few commenters encouraged CMS to refine the input for ultrasound room from 27 minutes to 29 minutes for CPT code 76641 and from 20 to 22 minutes for CPT code 76642 because ultrasound uses distinctive imaging equipment. All clinical labor tasks require usage of the machine, making the room unavailable during that time.

Response: The number of minutes assigned to the ultrasound room for both codes conforms to established times for highly technical equipment. We believe that adherence to these standard methodologies maintains relativity within the development of PE RVUs. Therefore, we are finalizing the interim final direct PE inputs for these services.

(16) CT Angiography (CTA) Head (CPT Codes 70496 and 70498)

In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work and direct PE input recommendations without refinement to establish interim final values for these codes.

Comment: Some stakeholders stated that clinical staff time for confirming prior images and reviewing patient clinical information was erroneously allocated to Rad Tech (L041B) instead of CT tech (L046A) and that CMS removed 2 minutes from clinical labor task “technologist QC”. Commenters suggested that both actions were inconsistent with other codes in the CTA family.

Response: We reviewed the interim final direct PE inputs as well as the “PE worksheet” that accompanied the RUC recommendation. We noted that the values in “CMS code” and “staff type” columns were discrepant for the two clinical labor tasks noted by the commenters. While the CMS code indicated L041B, the Staff Type indicated CT Tech. We have therefore corrected the CMS code from L041B to L046A to correspond to the clinical staff type. We reviewed the

direct PE database and confirmed that clinical labor task “Technologist QC’s images in PACS, checking for all images, reformats, and dose page” is included for these codes. We are finalizing the interim final values for these services, with the additional correction of the staff type discrepancy.

(17) Breast Tomosynthesis (CPT Codes 77061, 77062, and 77063)

In the CY 2015 PFS final rule with comment period, we assigned a PFS indicator of “I” to CPT codes 77061 and 77062 on an interim basis while awaiting recommendations from the RUC for all mammography services. Since CPT code 77063 is an add-on code and did not have an equivalent CY 2014 code, we believed it was appropriate to value it on an interim final basis in advance of receiving the RUC recommendations for other mammography services. We assigned it a CY 2015 interim final work RVU of 0.60 as recommended by the RUC. We also removed the equipment time for the PACS Workstation proxy from all three codes, and removed the time for task “Federally Mandated MQSA Activities Allocated To Each Mammogram” from CPT code 77063.

Comment: A commenter indicated that the direct PE input files included a PACS Workstation proxy for CPT code 77063, but did not allocate clinical staff time to this proxy.

Response: We removed the 4 minutes of clinical labor associated with “Federally Mandated MQSA Activities Allocated To Each Mammogram” due to the fact that CPT code 77063 is an add-on code, and this task would already have been performed previously with another mammography service. We did not assign equipment time for the PACS Workstation as we do not believe that its use would be typical for this procedure.

After consideration of comments received, we are finalizing the PFS indicator “I” for CPT codes 77061 and 77062, the interim final work RVU of 0.60 for CPT code 77063, and the interim final direct PE inputs for all three codes.

(18) Dosimetry (CPT Codes 77300, 77306, and 77307)

To establish interim final RVUs for these codes, we used the RUC-recommended work and direct PE inputs for these codes with PE refinements, with the refinement of consideration of the “record and verify system” as an indirect PE.

Comment: A few commenters expressed support for CMS’ adoption of the RUC-recommended work RVUs for CPT codes 77306 and 77307. Other commenters requested that CMS consider equipment item ED011 (record and verify) as a direct PE input because it is typically used during the procedures.

Response: We appreciate the commenters’ feedback related to these services. We reviewed the “record and verify” equipment item and agree with commenters that “record and verify” should be included as a direct PE to maintain consistency with other services in the direct PE database, and have updated the direct PE input database accordingly.

(19) Brachytherapy Isodose Plan (CPT Codes 77316, 77317, and 77318)

For CY 2015, the CPT Editorial Panel replaced six CPT codes (77305, 77310, 77315, 77326, 77327, and 77328) with five new CPT codes to bundle basic dosimetry calculation(s) with teletherapy and brachytherapy isodose planning. We established interim final work RVUs based on the RUC-recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316. Instead of using the RUC-recommended work RVU for CPT code 77316, a simple isodose planning code, we developed an interim final work RVU based on a direct crosswalk from the corresponding simple isodose planning code in the same family, CPT code 77306. Therefore, for CY 2015 we established an interim final work RVU of 1.40 for CPT code 77316. This approach is similar to the crosswalk the RUC used to develop the recommended work RVUs for CPT code 77318.

Comment: Commenters disagreed with CMS’ refinements to CPT code 77316 and stated that although CPT code 77316 is the simple isodose planning code in the family, the CMS-recommended crosswalk to CPT code 77306 does not accurately capture the intensity of the

procedure. Commenters suggested that CPT code 77316 is typically used for HDR brachytherapy with a single channel and more than four dwell positions. This requires more work than CPT code 77306, which is for external beam radiation planning. Commenters requested that CPT code 77316 be referred to the multispecialty refinement panel.

Response: Commenters did not provide new clinical information and, therefore we did not refer the codes to the multispecialty refinement panel. The RUC recommended a crosswalk for CPT code 77318 to CPT code 77307. We believe that if the work resources for the complex isodose planning codes are comparable between the two families, then the work resources between the simple isodose planning codes are also comparable. Therefore, we believe that the most accurate work RVU for CPT code 77316 is 1.40, based on a crosswalk to CPT code 77306.

Comment: Several commenters thanked CMS for adopting the RUC-recommended work RVUs for CPT codes 77317 and 77318.

Response: We appreciate the commenters' support. We are finalizing the CY 2015 interim final work RVUs as established.

(20) Electron Microscopy (CPT Code 88348)

We received PE-only recommendations for CPT code 88348 following the October 2013 RUC meeting. After reviewing these recommendations, we used the RUC recommendations without refinement to establish interim final values for CY 2015.

Comment: One commenter wrote to express their disagreement with the 79 percent reduction in the technical component of the procedure following the publication of the CY 2015 final rule. The commenter suggested that there was an error in evaluating the value and cost of this service, and provided additional information regarding the direct costs associated with providing electron microscopy to patients. The commenter stated that continued reduction in the value for CPT code 88348 will result in a reduction in the availability of tests which will provide

impaired service to many patients with treatable conditions and salvageable kidney function.

Response: We concur with the commenter on the importance of providing patient access to quality testing. However, we do not believe that there was an error in evaluating the value and cost of this service. We agreed with the RUC recommendations for direct PE inputs for CPT code 88348, and we continue to believe that these represent the most accurate values for this procedure.

(21) Microdissection (CPT Codes 88380 and 88381)

In reviewing the RUC recommendations for CPT code 88380, the work vignette indicated that the microdissection is performed by the pathologist. However, the PE worksheet also included several subtasks of “Microdissect each stained slide sequentially while reviewing H and E stained slide” that are performed by the cytotechnologist. Since we did not believe that both the pathologist and the cytotechnologist were completing these tasks, we did not allocate clinical labor time for the specific tasks we believe are completed by the pathologist. Table 31 of the CY 2015 final rule (FR 79 67697-67698) detailed our refinements to these clinical labor tasks. We accepted the RUC-recommended work RVU of 1.14 for CPT code 88380 and 0.53 for CPT code 88381 on an interim final basis for CY 2015.

Comment: A commenter urged CMS to accept and implement the practice expense inputs recommended by the RUC for CPT code 88380. For the clinical labor task “Dispose of razor blade, Cap tube and vortex specimens”, the commenter stated that the recommended 3 minutes for blade disposal tube capping is part of the processing of the individual specimen. The commenter suggested that the word "blade disposal" may have been confusing since it is not a cleaning function. The commenter requested that CMS restore the RUC-recommended 3 minutes for this task.

Response: We do not believe that clinical labor time should be assigned for this task, as CPT code 88380 uses a laser to perform the same activity. We do not believe that the use of a

razor blade, and associated clinical labor, would be typical for this procedure.

Comment: One commenter stated that the RUC recommended 18 minutes for the clinical labor task “Turn on dissecting microscope, place slide on scope, remove razor blade from box. Microdissect tissue within etched area, while viewing slide under dissecting scope, place tissue into cap of collection tube with blade. Repeat this step for seven other slides.” The commenter indicated that the cytotechnologist and pathologist are working together during this task, and the assistance of the cytotechnologist is necessary during these ancillary tasks for the efficiency of the dissection process. The work survey results indicated that some of the work time has shifted to the clinical labor time for this particular task.

Response: We continue to believe that the pathologist is the individual performing this clinical labor task, not the cytotechnologist.

Comment: One commenter disagreed with the CMS refinement to the equipment time for the Veritas microdissection instrument (EP087). The commenter stated that the equipment time associated with EP087 is the sum of time to prepare the instrument for use, plus the time the pathologist and cytotechnologist are using it, plus the time the room and equipment are cleaned. The commenter suggested that while microdissection is taking place, the equipment cannot be used for any other purpose. The commenter indicated that the sum of these time increments equals 34 minutes, not the 32 minutes as refined by CMS.

Response: We appreciate the commenter’s assistance in providing clarification regarding the appropriate equipment time for EP087. After consideration of comments received, we agree that the Veritas microdissection instrument would typically be in use for 33 minutes of intraservice time, plus 3 minutes for laser preparation, plus one minute for room cleaning following equipment use. Therefore, we are refining the equipment time for EP087 to 37 minutes for CPT code 88380, to match the standard equipment time formula, and finalizing all other direct PE inputs as established as interim final.

(22) Electro-oculography (EOG VNG) (CPT Code 92543)

We established a work RVU of 0.10 for CPT code 92543 as interim final for CY 2015. Several commenters disagreed with our interim final values. However, the CPT Editorial Panel deleted CPT code 92543 for CY 2016; we refer readers to section II.H. of this final rule with comment period, where we discuss CPT codes 9254A and 9254B, used to report related services.

(23) Doppler Echocardiography (CPT Codes 93320, 93321 and 93325)

As detailed in the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVUs for CPT codes 93320, 93321 and 93325, based upon the RUC-recommended work RVUs. In establishing interim final direct PE inputs for CY 2015, we refined the RUC's recommendations for CPT codes 93320, 93321 and 93325 by removing the minutes associated with equipment item ED021 (computer, desktop, w/monitor) since a computer is included in the other equipment inputs associated with codes.

Comment: One commenter supported CMS' adopting the work RVUs and times recommended by the RUC for these services (CPT codes 93320, 93321, and 93325).

Response: We appreciate the commenters support. We are finalizing the CY 2015 interim final work RVUs as established.

Comment: One commenter stated that ED021 is not included in the room.

Response: We disagree that "computer, desktop w/monitor" (ED021) is not included in the equipment room "room, vascular ultrasound." The PE reference materials submitted by the RUC indicate that "ultrasound room, vascular" includes a computer (Vascoguard II, main station with cart, keyboard, LCD monitor, deskjet printer, Doppler, and probe holder). Therefore, we are finalizing the direct PE inputs for CPT codes 93320, 93321, and 93225 as established as interim final.

(24) Interventional Transesophageal Echocardiography (TEE) (CPT Codes 93312, 93313, 93314, 93315, 93316, 93317, 93318 and 93355)

For CY 2015, we used the RUC-recommended work RVU of 2.40 to establish an interim final value for CPT code 93318 and 4.66 for CPT code 93355. Based on a crosswalk from CPT code 75573, we assigned CPT code 93312 a CY 2015 interim final work RVU of 2.55. We noted that based on the CPT descriptor for CPT code 93315, we believed that the appropriate work for this service was reflected in the combined work of CPT codes 93316 and 93317, resulting in a CY 2015 interim final work RVU of 2.94. For CPT codes 93313, 93314, 93316 and 93317, we assigned CY 2015 interim final work RVUs that corresponded to the 25th percentile survey result. Each of these codes had a significant reduction in intraservice time since the last valuation. We noted that we believe the 25th percentile survey values better describe the work and time involved in these procedures than the RUC recommendations, and that it helps maintain appropriate relativity in the family. Additionally, we refined the preservice and intraservice times for CPT codes 93314 and 93317 to 10 and 20 minutes, respectively, to maintain relativity among the interim final work RVUs and times.

Comment: Some commenters disagreed with CMS' decision to value the work RVU for CPT code 93312 by crosswalking it from CPT code 75573, rather than the RUC-recommended work RVU based on a crosswalk from CPT code 43247 (Esophagogastroduodenoscopy).

Response: The RUC-recommended crosswalk code, CPT code 43247, is a 0-day global service, whereas CPT code 75573 has no global period. Since CPT code 75573 and CPT code 93312 do not have global periods, while 43247 has a global period, we do not believe that the latter code can serve as an appropriate crosswalk. Therefore, we are finalizing the CY 2015 work RVUs as established for CPT code 93312.

Comment: A few commenters disagreed with CMS' refinement of the work RVUs for CPT codes 93313 and 93314. The commenters stated that the work RVU that corresponds to the 25th percentile survey result fails to account for changes in technique, technology, and knowledge.

Response: After review of the comments, we continue to believe that the RUC-recommended work RVUs do not adequately reflect the significant reduction in intraservice time, and that our corresponding refinements to the work RVUs are appropriate. We do not believe that the work RVUs corresponding to the survey 25th percentile result fail to account for typical changes in technique, technology, and knowledge. Therefore, we are finalizing the CY 2015 work RVUs as established for CPT codes 93313 and 93314.

Comment: A few commenters disagreed with the time refinement made to CPT codes 93314 and 93317.

Response: To maintain consistency with the work RVUs, we continue to believe that these time refinements are appropriate. Therefore, we are finalizing the times for CPT codes 93314 and 93317 as established for CY 2015.

Comment: Some commenters disagreed with CMS' use of the BBM to determine a work RVU for CPT code 93315, suggesting that it did not incorporate updated service times and changes in technique, technology, and knowledge.

Response: After consideration of the comments received, we continue to believe that the appropriate work RVU for CPT code 93315 is reflected in the combined work of CPT codes 93316 and 93317, resulting in a CY 2015 interim final work RVU of 2.94. We are finalizing the interim final work RVUs for these codes as established.

Comment: A commenter requested that this family of codes be referred to the multispecialty refinement panel.

Response: The request for referral to the multispecialty refinement panel did not include new clinical information; therefore, the request did not meet the criteria for review by the multispecialty refinement panel.

Comment: One commenter questioned why the TC codes within the congenital TEE family are contractor-priced.

Response: We did not receive recommendations for the direct PE inputs for CPT codes 93315, 93317, and 93318. Without such recommendations, we did not have sufficient information about the resource costs necessary to establish national pricing and we therefore assigned a contractor-priced status to the technical component of these codes. We are finalizing the contractor-priced status for the technical component of CPT codes 93315, 93317, and 93318.

Comment: One commenter supported CMS' proposal to adopt the RUC-recommended work RVU and times for CPT code 93355.

Response: We appreciate the commenter's feedback, and we are finalizing the CY 2015 work RVUs and direct PE inputs as established as interim final.

(25) Duplex Scans (CPT Codes 93880, 93882, 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979)

For CY 2014, we maintained the CY 2013 RVUs for CPT codes 93880 and 93882. As we stated in the CY 2014 PFS final rule with comment period (78 FR 74342), we were concerned that the RUC-recommended work RVUs for CPT codes 93880 and 93882, as well as our final work RVUs for CPT codes 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) and 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study) did not maintain the appropriate relativity within the family. We referred the entire family to the RUC to assess relativity among the codes and to recommend appropriate work RVUs. We also requested that the RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study) in conjunction with the duplex scan codes to assess the relativity between and among the codes. In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work RVUs for CPT codes 93880, 93882, 93925, and 93926 while making several standard PE refinements consistent with standard inputs for digital imaging and our policies for not allocating quality assurance

documentation to individual services as a direct expense.

Comment: Some commenters stated that quality assurance (QA) documentation is an integral part of the procedure, so it should be included as a direct PE input clinical labor task.

Response: We consider QA documentation to be an indirect PE since it is not generally allocated to a single patient during an individual procedure. Instead, we believe QA activities are undertaken through different means across a wide range of practices.

Comment: One commenter disagreed with the minutes assigned to the vascular ultrasound room (EL016) for CPT code 93880. The commenter disagreed with the CMS refinement from 68 minutes of equipment time to 51 minutes, and objected to the removal of equipment time for preservice tasks not typically associated with highly technical equipment. The commenter stated that there was no data to support the CMS rationale, and presented survey data suggesting that preservice activities are routinely carried out in the vascular ultrasound room.

Response: We continue to 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 and are typically available for other patients even when one member of the clinical staff may be occupied with a pre-service or post-service task related to the procedure. 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).

Comment: A few commenters stated that a desktop computer is a necessary PE input for these codes.

Response: We believe that computer processing functionality is inherent in the ultrasound system included in the general ultrasound room. We refer readers to Table 14 for the items and associated prices that constitute the ultrasound rooms.

TABLE 14: Items that Constitute the Ultrasound Rooms

\$369,945	General Ultrasound Room, General
\$220,000	GE Logic 9 ultrasound system (H4902SG)
\$18,000	transducer, 3-8MHz matrix array convex (H40412LC)
\$650	probe starter kit for H40412LD: bracket, needle guides, probe covers (E8385RF)
\$18,000	transducer, 5-13MHz linear matrix array (H40412LD)
\$650	probe starter kit for H40412LD: bracket, needle guides, probe covers (E8385RF)
\$12,000	transducer, 4-10MH micro convex probe (H40412LE)
\$11,000	transducer, 4-10MHz probe (H40412LG)
\$10,000	transducer, 2-5MHz probe (H4901PE)
\$12,500	software, B-flow (H4901BF)
\$5,500	software, DICOM (H4901DM)
\$8,000	software, LOGIQ View (h4901LW)
\$4,900	VHS video recorder (Sony SVO-9500MD/2)
\$6,500	digital printer (Sony UPD21)
\$1,995	monochrome thermal printer (Sony UPD895)
\$5,250	ultrasound table (E8375F)
\$35,000	compound imaging
\$466,492	Ultrasound Room, Vascular
	General Ultrasound Room, General
	Nicojet VasoGuard P84 (PPG & lower extremity):
	Nicolet Pioneer TC 8080 (transcranial)
	Atrium Medical Vaslab - software add-on for data collection, database maintenance, and accreditation processing.

In the CY 2014 PFS final rule with comment period (78 FR 74342), we requested that the RUC assess the relativity among the entire family of duplex scans codes and recommend appropriate work RVUs. We also requested that the RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study) in conjunction with the duplex scan codes to assess the relativity between and among those codes. For CY 2015, we established the RUC-recommended work RVUs as interim final for all of the codes in the family except CPT codes 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979. For several codes in this family with 10 minutes of intraservice time, the RUC recommended 0.50 work RVUs. CPT

code 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), CPT code 93979 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study,) and CPT code 93888 all have 10 minutes intraservice time and we assigned them an interim final work RVU of 0.50. For several codes in this family with 15 minutes of intraservice time, the RUC recommended work RVUs that corresponded to the 25th percentile survey result. We found this to appropriately reflect the work involved and applied the same logic to other codes with 15 minutes of intraservice time. We established the work RVUs for CPT codes 93975, 93976, and 93978 that corresponded to the 25th percentile survey result, which all have 15 minutes of intraservice time. Therefore, for CY 2015 we established the following interim final work RVUs: 1.16 for CPT code 93975; 0.80 for CPT code 93976; 0.80 for CPT code 93978; and 0.50 for CPT code 93979.

Comment: Several commenters disagreed with the allocation of 0.50 RVUs to codes with 10 minutes of intraservice time across the Doppler/duplex code family. The commenters suggested that 0.50 RVUs does not reflect the relationship between the codes based on their time, intensity, rank order, and complexity. Commenters stated that transcranial Doppler studies are more intense than Doppler studies of other body parts and thus should be valued with higher RVUs. Commenters requested that CPT codes 93886 and 93888 be referred to the multispecialty refinement panel.

Response: When valuing these codes, we used the RUC recommendation of 0.80 RVUs for CPT code 93880, which has an intraservice time of 15 minutes. Applying the work RVU-to-time ratio of CPT code 93880 to CPT code 93886, which has an intraservice time of 17 minutes, results in our interim final work RVU of 0.91 for CPT code 93886. For CPT code 93888, we noted that it had an identical time and similar intensity to code 93882; therefore, we found an RVU of 0.50 to be appropriate. The commenters did not include any new clinical information in their requests for referral of CPT codes 93886 and 93888. Therefore, the requests did not meet

the criteria for referral to the multispecialty refinement panel.

Comment: Several commenters encouraged CMS to adopt the RUC recommendation for CPT code 93926, stating that, although CPT code 93926 has 10 minutes of intraservice time, the intensity is greater than 0.50 RVUs.

Response: We appreciate the commenters' feedback. However, we believe that 0.50 is the accurate work RVU for CPT code 93926 based on a crosswalk from CPT code 93880. We believe that because the intensity is similar and the overall time is the same, the overall work is comparable.

Comment: Several commenters pointed out that CPT code 93975 has 20 minutes of intraservice time, and should not have the same RVU as a code with 15 minutes of intraservice time. A few commenters suggested that CPT code 93976 involves arterial and venous blood flow and is therefore more intense than other procedures in the code family. Commenters requested that CPT codes 93975 and 93976 be referred to the multispecialty refinement panel.

Response: When valuing code 93965, we noted that we did not think the RVU that resulted in application of the intraservice ratio to 93880 accurately reflected the work involved in furnishing the procedure. Therefore, we used the work RVU that corresponded to the 25th percentile survey result to establish the RVU. For code 93976, we noted that the intraservice time is identical to CPT code 93880, which has a work RVU of 0.50. This value also corresponds to the 25th percentile survey result.

Comment: A commenter commended CMS for accepting the RUC-recommended work RVU for CPT code 93931.

Response: We appreciate the commenter's feedback and support.

After considering these comments, we are finalizing the CY 2015 interim final values as established.

(26) Carotid Intima-Media Thickness Ultrasound (CPT Code 93895)

For CY 2015, the CPT Editorial Panel created new CPT code 93895 to describe the work of using carotid ultrasound to measure atherosclerosis and quantify the intima-media thickness. After review of this code, we determined that it was used only for screening, and therefore, we assigned a PFS procedure status indicator of N (Noncovered service) to CPT code 93895.

Comment: Two commenters were dissatisfied with our designation of this service as a noncovered screening tool. One commenter stated that “other methods for atherosclerosis imaging are already approved for coverage under Medicare local coverage determination policies and are directly comparable to carotid atherosclerosis imaging in terms of their purpose and clinical application.” Another commenter suggested that the test was “designed to be used in patients with cardiovascular risk to enhance care and assist physicians in selection and intensity of risk reducing therapies.” All commenters encouraged CMS to reconsider its decision to classify CPT code 93895 as a noncovered screening service.

Response: While we appreciate the commenter’s feedback, we are unaware of other carotid atherosclerosis imaging services for which we provide payment when used for patients without signs or symptoms of disease. Information that we received from the RUC and specialty societies indicated that the typical patient would be one without signs or symptoms of carotid disease. Therefore, this test does not meet the statutory definition of a diagnostic test and as such, is not covered under Medicare.

(27) Negative Pressure Wound Therapy (CPT Codes 97605, 97606, 97607 and 97608)

Prior to CY 2013, CPT codes 97605 and 97606 were both used to report negative pressure wound therapy, which were typically reported in conjunction with durable medical equipment that was separately payable. In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (Negative pressure wound therapy, (for example, vacuum assisted drainage

collection) using a mechanically powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and G0457 (Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm).

For CY 2015, the CPT Editorial Panel created CPT codes 97607 and 97608 to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 and 97606 were revised to specify the use of durable medical equipment. Based upon the revised coding scheme for negative pressure wound therapy, we deleted the G-codes. We contractor-priced CPT codes 97607 and 97608 for CY 2015 and the CPT codes were designated “Sometimes Therapy” on our Therapy Code List, consistent with the G-codes.

Comment: One commenter was disappointed with CMS’ decision to contractor price CPT Codes 97607 and 97608, since CMS originally created G-codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries through means unrelated to the durable medical equipment benefit. They expressed concern that practitioners who utilize the new disposable device will be paid amounts derived from crosswalks from the DME-related codes (CPT codes 97605 and 97606), which include more work time and work.

Response: We agree that the codes are intended to provide a payment mechanism for negative pressure wound therapy services furnished to a beneficiary using equipment that is not paid for as durable medical equipment. However, we do not agree that contractor pricing the codes is unlikely to result in accurate payment amounts for the services. There are several obstacles to developing accurate payment rates for these services within the PE RVU

methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services. Since our methodology values services based on the typical case, and the cost structure differs among a variety of products, we believe that contractor pricing allows for more accurate payment than national prices that would be based on the cost structure of a single product. Thus, contractor pricing these codes allows for flexibility in the products used, pending additional information about what product is typically involved in furnishing these services.

Comment: One commenter expressed disappointment that CMS had adjusted the equipment and staff time downward for CPT codes 97605 and 97606. The commenter expressed that the timing of the publication of this rule does not allow adequate time to evaluate the impact these changes will have on operating expenses and noted that the complicated nature of the formula used to calculate PE RVUs limits their ability to predict the impact of these changes.

Response: The intraservice clinical labor time already included time for wound checking. As a result, the 5 minutes in the post-service period were refined to 2 minutes. Accordingly, equipment times were refined to conform to the changes in clinical labor time. After consideration of the comment, we are finalizing the direct PE inputs for CPT codes 97605 and 97606 as established. In response to the commenter's concerns regarding the timing of changes in values for particular PFS services, we note that beginning in rulemaking for CY 2017, we anticipate that most changes in payment based on review of individual codes will be proposed in the annual PFS proposed rule instead of established as interim final in the annual final rule. We also note that we display the resulting PE RVUs for each code in Addendum B for each proposed and final rule. This allows stakeholders to see the PE RVUs that result from any changes in input assumptions for particular codes.

(28) Hyperbaric Oxygen Therapy (HBOT) (CPT Code 99183 and HCPCS Code G0277)

For CY 2015, we received RUC recommendations for CPT code 99183 that included significant increases to the direct PE inputs, which assumed a treatment time of 120 minutes. Prior to CY 2015, CPT code 99183 was used to report both the professional attendance and supervision, and the costs associated with treatment delivery were included in nonfacility direct PE inputs for the code. We created HCPCS code G0277 to be used to report the treatment delivery separately, consistent with the OPPS coding mechanism, to allow the use of the same coding structure across settings. In establishing interim final direct PE inputs for HCPCS code G0277, we used the RUC-recommended direct PE inputs for CPT code 99183 and adjusted them to align with the 30-minute treatment interval. We observed that the quantity of oxygen increased significantly relative to the previous value. To better understand this change, we reviewed the instruction manual for the most commonly used HBOT chamber, which provided guidance regarding the quantity of oxygen used. Based on our review, we determined that 12,000, rather than 47,000, was the typical number of units. Therefore, in aligning the direct PE inputs as described above, we first adjusted the units of oxygen to 12,000 for the recommended 120-minute time, and subsequently adjusted it to align with the 30 minute G-code.

Comment: Several commenters disagreed with the volume of oxygen consumed for a 120 minute treatment time cited in the final rule and some recommended adopting 42,000-47,000 liters or units for a typical 120-minute HBO2 profile. We also received a few additional comments on these services during the comment period for the proposed rule. The commenters reiterated that they support the change from C1300 to G0277 as the 30 minute interval for hyperbaric oxygen therapy; however, they suggested that the methodology used by the RUC more accurately reflects the amount of oxygen that is used in a hyperbaric oxygen treatment. They stated, “the provision of a hyperbaric oxygen treatment requires a pressure of greater than 1.4 ATA and a therapeutic dose of as close to 100 percent oxygen as can be achieved in the monoplace environment. This level of oxygen delivery must be reached and maintained for the

duration of the designated treatment time. Therefore, a treatment of 2.4 ATA for 120 minutes will require that the target chamber oxygen concentration must be achieved at the same time as the designated pressure.” The commenter additionally requested that CMS not finalize the proposed CY 2016 reduction in PE RVUs.

Response: We thank the commenters for their feedback and have considered the materials submitted. We agree that a high purge flow rate is needed in order to reach maximum pressure/O₂; however, we still have not seen data that demonstrates the need to continue a maximum flow rate throughout the entire session. The RUC forwarded an invoice for the Sechrist Model 3600E Hyperbaric Chamber for use in pricing the capital equipment for this service. According to the manufacturer’s manual for this model, “once the nitrogen has been purged from the chamber and the internal oxygen concentration has exceeded 95 percent, high flows are no longer needed to maintain the patient’s saturation level.” The manual also states that “the plateau purge flow can be set to 80 lpm.” We calculated that 13 minutes at 400 lpm plus 120 minutes at 80 lpm equals 14,800 liters of oxygen. Based on the current publicly available information in the manufacturer’s manual, we believe that this represents the typical usage for a 120 minute treatment. This amount represents an increase from the interim final amount of 12,000. As we described in the CY 2015 final rule, we aligned this total oxygen requirement to the 30 minute G-code. Following that principle here, we are updating the direct PE inputs to 3,700 liters of oxygen for HCPCS code G0277. In response to the commenter’s request regarding a reduction in the PE RVUs in the CY 2016 PFS proposed rule, any changes from the CY 2015 PE RVUs for HCPCS code G0277 to values displayed in association with the CY 2016 proposed rule resulted from overall changes in PE relativity and PFS budget neutrality and did not result from a change in the direct PE inputs.

9. CY 2016 Interim Final Codes

For recommendations regarding any new or revised codes received after the February 10, 2015 deadline, including updated recommendations for codes included in the CY 2016 proposed rule, we are establishing interim final values in this final rule with comment period, consistent with previous practice.

We note that in the CY 2016 PFS proposed rule, we inadvertently published work RVUs for several CPT codes in Addendum B that were not explicitly discussed in the text. Those CPT codes include 88341, 88364, and 88369; these codes had previously been proposed on an interim basis in the CY 2015 PFS final rule with comment period. While these codes were not discussed in the proposed rule because our files displayed incorrect work RVUs for these codes due to the data error, some commenters raised questions about these codes' displayed work RVUs. To allow public comment on the correct valuations, we are therefore establishing interim final work RVUs for these codes for CY 2016 and requesting comment on those interim final values in this final rule. We will respond to comments on these values in CY 2017 rulemaking.

TABLE 15: CY 2016 Interim Final Work RVUs for New/Revised or Potentially Misvalued Codes

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
10035	Placement of soft tissue localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion	NEW	1.70	1.70	No
10036	Placement of soft tissue localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; each additional lesion	NEW	0.85	0.85	No
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land);	10.62	10.03	9.56	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/ HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
	primary, without free graft, each tendon				
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, without free graft, each tendon	8.77	11.50	10.53	No
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, with free graft (includes obtaining graft), each tendon	9.36	13.10	12.13	No
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session	4.51	3.50	3.50	No
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	NEW	9.00	7.75	Yes
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access	NEW	1.80	1.80	No
47532	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram)	NEW	4.25	4.25	No
47533	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external	NEW	6.00	6.00	No
47534	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external	NEW	8.03	8.03	No
47535	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external	NEW	4.50	4.50	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/ HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
47536	Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation	NEW	2.88	2.88	No
47537	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation	NEW	1.83	1.83	No
47538	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access	NEW	6.60	6.60	No
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter	NEW	9.00	9.00	No
47540	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)	NEW	12.00	10.75	No
47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access	NEW	5.61	5.61	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/ HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
47542	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct	NEW	3.28	2.50	No
47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple	NEW	3.51	3.07	No
47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)	NEW	4.74	4.29	No
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	NEW	2.78	2.35	No
50606	Endoluminal biopsy of ureter and/or renal pelvis, non-endoscopic, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation	NEW	3.16	3.16	No
50705	Ureteral embolization or occlusion, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation	NEW	4.03	4.03	No
50706	Balloon dilation, ureteral stricture, including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation	NEW	3.80	3.80	No
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	32.06	26.80	21.36	No
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)	NEW	17.00	15.00	Yes

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/ HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory	NEW	12.00	10.00	Yes
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to the primary code)	NEW	5.50	4.25	No
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)	NEW	1.75	1.75	No
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s), (includes imaging guidance, when performed)	NEW	1.10	1.10	No
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)	NEW	1.90	1.81	No
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve	2.36	2.36	2.36	No
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	2.32	2.32	2.32	No
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	0.60	0.60	0.60	No
65778	Placement of amniotic membrane on the ocular surface; without sutures	1.19	1.00	1.00	No
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	3.92	2.50	2.50	Yes
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	10.73	8.80	7.81	No
65855	Trabeculoplasty by laser surgery	3.99	3.00	2.66	No
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery	15.02	13.94	11.27	No
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)	18.86	14.81	12.57	No
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of	16.71	16.00	14.06	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
	subretinal fluid				
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique	22.89	17.13	15.19	No
67110	Repair of retinal detachment; by injection of air or other gas (eg, pneumatic retinopexy)	10.25	10.25	8.31	No
67113	Repair of complex retinal detachment (eg, proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens	25.35	19.00	19.00	No
67227	Destruction of extensive or progressive retinopathy (eg, diabetic retinopathy), cryotherapy, diathermy	7.53	3.50	3.50	No
67228	Treatment of extensive or progressive retinopathy (eg, diabetic retinopathy), photocoagulation	13.82	4.39	4.39	No
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No
73501	Radiologic examination, hip, unilateral, with pelvis when performed; 1 view	NEW	0.18	0.18	No
73502	Radiologic examination, hip, unilateral, with pelvis when performed; 2-3 views	NEW	0.22	0.22	No
73503	Radiologic examination, hip, unilateral, with pelvis when performed; minimum of 4 views	NEW	0.27	0.27	No
73521	Radiologic examination, hips, bilateral, with pelvis when performed; 2 views	NEW	0.22	0.22	No
73522	Radiologic examination, hips, bilateral, with pelvis when performed; 3-4 views	NEW	0.29	0.29	No
73523	Radiologic examination, hips, bilateral, with pelvis when performed; minimum of 5 views	NEW	0.31	0.31	No
73551	Radiologic examination, femur; 1 view	NEW	0.16	0.16	No
73552	Radiologic examination, femur; minimum 2 views	NEW	0.18	0.18	No
74712	Magnetic resonance (eg, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation	NEW	3.00	3.00	No
74713	Magnetic resonance (eg, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation	NEW	1.85	1.78	No
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed	11.32	8.78	8.00	No
77790	Supervision, handling, loading of radiation	1.05	0.00	0.00	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
78264	Gastric emptying imaging study (eg, solid, liquid, or both)	0.80	0.80	0.74	No
78265	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel transit, up to 24 hours	NEW	0.98	0.98	No
78266	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel and colon transit, multiple days	NEW	1.08	1.08	No
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation	0.56	0.56	0.56	No
88106	Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation	0.37	0.37	0.37	No
88108	Cytopathology, concentration technique, smears and interpretation (eg, Saccomanno technique)	0.44	0.44	0.44	No
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal	0.56	0.56	0.56	No
88160	Cytopathology, smears, any other source; screening and interpretation	0.50	0.50	0.50	No
88161	Cytopathology, smears, any other source; preparation, screening and interpretation	0.50	0.50	0.50	No
88162	Cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains	0.76	0.76	0.76	No
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report	0.30	0.27	0.27	No
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive	NEW	0.17	0.17	No
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	0.78	0.78	0.78	No

HCPCS Code	Long Descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
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	0.80	0.80	0.80	No
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method	3.09	3.09	3.09	No

TABLE 16: CY 2016 Interim Final 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
10035	Perq dev soft tiss 1st imag	ED050	PACS Workstation Proxy	NF		48	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.04)
		EQ168	light, exam	NF		26	43	Refined equipment time to conform to established policies for non-highly technical equipment	\$ 0.07
		L051B	RN/Diagnostic Medical Sonographer	NF	Review/read X-ray, lab, and pathology reports	2	0	Clinical labor task redundant with clinical labor task Review examination with interpreting MD	\$ (1.02)
10036	Perq dev soft tiss add imag	ED050	PACS Workstation Proxy	NF		26	25	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.02)
		EQ168	light, exam	NF		21	22	Refined equipment time to conform to	\$ 0.00

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
								established policies for non-highly technical equipment	
		L051B	RN/Diagnostic Medical Sonographer	NF	Review/read X-ray, lab, and pathology reports	1	0	Clinical labor task redundant with clinical labor task Review examination with interpreting MD	\$ (0.51)
41530	Tongue base vol reduction	EQ214	radiofrequency generator (NEURO)	NF		83	0	Equipment item replaced by another item (NEW)	\$ (10.58)
		EQ374	radiofrequency generator (Gyrus ENT G3 workstation)	NF		0	83	Equipment item replaces another item (EQ374)	\$ 3.29
47531	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.11)
		EF018	stretcher	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.03)
		EF027	table, instrument, mobile	NF		92	87	Refined equipment	\$ (0.01)

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
								time to conform to established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.07)
		EQ032	IV infusion pump	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.03)
		EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.05)
		L037D	RN/LPN/MTA	NF	Assist physician in performing	20	0	Removed clinical labor associated with moderate sedation;	\$ (7.40)

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
					procedure			moderate sedation not typical for this procedure	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	\$ (1.02)
47532	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		76	73	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		292	289	Refined equipment time to conform to established policies for equipment with	\$ (0.00)

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
								4x monitoring time	
		EL011	room, angiography	NF		52	49	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		76	67	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		76	67	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (1.05)

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
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
47533	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		96	93	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		312	309	Refined equipment time to conform to established policies	\$ (0.00)

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
								for equipment with 4x monitoring time	
		EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		96	87	Refined equipment time to conform to established policies for non-highly	\$ (1.05)

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
								technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
47534	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		114	111	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		330	327	Refined equipment	\$ (0.00)

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
								time to conform to established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		90	87	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		114	105	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		114	105	Refined equipment time to conform to established policies	\$ (1.05)

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
								for non-highly technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
47535	Conversion ext bil drg cath	ED050	PACS Workstation Proxy	NF		81	78	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)

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
		EF027	table, instrument, mobile	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.00)
		EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		81	72	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipme	6	3	Refined time to standard for this	\$ (1.23)

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
					nt by physician staff			clinical labor task	
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
47536	Exchange biliary drg cath	ED050	PACS Workstation Proxy	NF		66	63	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		162	159	Refined equipment time to conform to established policies for equipment with	\$ (0.00)

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
								4x monitoring time	
		EL011	room, angiography	NF		42	39	Refined equipment time to conform to changes in clinical labor time EL014	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		66	57	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious	\$ (1.60)

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
								sedation pack conscious sedation pack SA044	
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack SA044	\$ (4.67)
47537	Removal biliary drg cath	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.11)
		EF018	stretcher	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.03)
		EF027	table, instrument, mobile	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.01)
		EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical	\$ (15.76)

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
								labor time	
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.07)
		EQ032	IV infusion pump	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.03)
		EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.05)
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	\$ (7.40)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change
			NIBP, temp, resp)					time to conform to established policies for equipment with 4x monitoring time	
		EQ032	IV infusion pump	NF		307	304	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		91	82	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack (SA044)	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation	\$ (4.67)

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
								labor time	
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		116	107	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		116	107	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (1.05)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is	\$ (1.60)

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
								included in conscious sedation pack SA044	
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
		SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	\$ 130.00
		SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	\$ (487.00)
47540	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		126	123	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ (0.07)
		EF018	stretcher	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		342	339	Refined equipment time to conform to	\$ (0.00)

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
								established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		102	99	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EQ168	light, exam	NF		126	117	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		126	117	Refined equipment time to conform to established policies for non-highly	\$ (1.05)

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
								technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
		SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	\$ 130.00
		SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	\$ (487.00)
47541	Plmt access bil tree sm bwl	ED050	PACS Workstation Proxy	NF		96	93	Refined equipment time to conform to established policies for PACS	\$ (0.07)

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
								Workstation Proxy	
		EF018	stretcher	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)
		EF027	table, instrument, mobile	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.00)
		EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	\$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.04)
		EQ032	IV infusion pump	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ (0.02)

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		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (0.04)
		EQ250	ultrasound unit, portable	NF		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	\$ (1.05)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	\$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	\$ (4.67)
47542	Dilate biliary	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see	\$ 65.00

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
	duct/ampulla							preamble SD152	
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	\$ (243.50)
47544	Removal duct glbl dr calculi	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	\$ 65.00
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	\$ (243.50)
49185	Sclerotx fluid collection	EF018	stretcher	NF		60	76	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ 0.08
		EF027	table, instrument, mobile	NF		99	115	Refined equipment time to conform to established policies for equipment with 4x monitoring time	\$ 0.02
		EQ168	light, exam	NF		39	115	Refined equipment time to conform to established policies for equipment with	\$ 0.33

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
								4x monitoring time	
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	0	Clinical labor task redundant with clinical labor task Assist physician in performing the procedure L041B	\$ (11.10)
		SB024	gloves, sterile	NF		4	2	Aligned supply quantities with changes to number of clinical labor staff	\$ (1.68)
50606	Endoluminal bx urtr rml plvs	EF027	table, instrument, mobile	NF		46	45	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.00)
		EL011	room, angiography	NF		46	0	Equipment item replaced by another item EL014	\$ (241.71)
		EL014	room, radiographic-fluoroscopic	NF		0	47	Equipment item replaces another item EL011	\$ 65.48
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		46	45	Refined equipment time to conform to established policies	\$ (0.01)

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
								for moderate sedation equipment	
		EQ032	IV infusion pump	NF		46	45	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.01)
		EQ168	light, exam	NF		46	49	Refined equipment time to conform to established policies for non-highly technical equipment	\$ 0.01
50705	Ureteral embolization/occl	EF027	table, instrument, mobile	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.00)
		EL011	room, angiography	NF		61	0	Equipment item replaced by another item EL014	\$ (320.54)
		EL014	room, radiographic-fluoroscopic	NF		0	62	Equipment item replaces another item EL011	\$ 86.37
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		61	60	Refined equipment time to conform to	\$ (0.01)

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
								established policies for moderate sedation equipment	
		EQ032	IV infusion pump	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.01)
		EQ168	light, exam	NF		61	64	Refined equipment time to conform to established policies for non-highly technical equipment	\$ 0.01
50706	Balloon dilate urtrlistrix	EF027	table, instrument, mobile	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.00)
		EL011	room, angiography	NF		61	0	Equipment item replaced by another item EL014	\$ (320.54)
		EL014	room, radiographic-fluoroscopic	NF		0	62	Equipment item replaces another item EI011	\$ 86.37
		EQ011	ECG, 3-channel (with SpO2,	NF		61	60	Refined equipment	\$ (0.01)

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
			NIBP, temp, resp)					time to conform to established policies for moderate sedation equipment	
		EQ032	IV infusion pump	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	\$ (0.01)
		EQ168	light, exam	NF		61	64	Refined equipment time to conform to established policies for non-highly technical equipment	\$ 0.01
		SD019	catheter, balloon, ureteral-GI (strictures)	NF		0	1	Supply item replaces another item; see preamble SD152	\$ 166.00
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD019	\$ (243.50)
65779	Cover eye w/membrane suture	EQ137	instrument pack, basic (\$500-\$1499)	NF		62	56	Refined equipment time to conform to established policies for surgical instrument packs	\$ (0.01)

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
		L038A	COMT/COT/RN/CST	F	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)	6	0	Aligned discharge day management clinical labor time with the discharge day management work time	\$ (2.28)
66170	Glaucoma surgery	EL005	lane, exam (oph)	F		297	288	Refined equipment time to conform to office visit duration	\$ (0.86)
		L038A	COMT/COT/RN/CST	F	99212 27 minutes	3	4	Refined clinical labor to align with number of post-operative visits	\$ 10.26
		L038A	COMT/COT/RN/CST	F	99213 36 minutes	6	5	Refined clinical labor to align with number of post-operative visits	\$ (13.68)
		SA050	pack, ophthalmology visit (no dilation)	F		3	4	Refined supply quantity to align with number of post-operative visits	\$ 1.19
		SA082	pack, ophthalmology visit (w-dilation)	F		6	5	Refined supply quantity to align with number of post-operative visits	\$ (2.00)

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
								codes in the family	
78264	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		74	70	See preamble text Non-standard equipment time formula	\$ (0.84)
		ED050	PACS Workstation Proxy	NF		82	98	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ 0.35
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist	4	2	Refined time to standard for this clinical labor task	\$ (1.23)
78265	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		88	84	See preamble text Non-standard equipment time formula	\$ (0.84)
		ED050	PACS Workstation Proxy	NF		98	115	Refined equipment time to conform to	\$ 0.37

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
								established policies for PACS Workstation Proxy	
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist	4	2	Refined time to standard for this clinical labor task	\$ (1.23)
78266	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		109	105	See preamble text Non-standard equipment time formula	\$ (0.84)
		ED050	PACS Workstation Proxy	NF		119	130	Refined equipment time to conform to established policies for PACS Workstation Proxy	\$ 0.24
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by	4	2	Refined time to standard for this clinical labor task	\$ (1.23)

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
					physician				
88106	Cytopath fl nongyn filter	EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18
88108	Cytopath concentrate tech	EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	\$ (0.33)

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
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18
		SB022	gloves, non-sterile	NF		0.2	2	See preamble text	\$ 0.15
		SB027	gown, staff, impervious	NF		0.2	2	See preamble text	\$ 2.13
		SM016	eye shield, splash protection	NF		0.2	1	See preamble text	\$ 1.18
88112	Cytopath cell enhance tech	EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	\$ (0.33)

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
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18
		SB022	gloves, non-sterile	NF		0.2	2	See preamble text	\$ 0.15
		SB027	gown, staff, impervious	NF		0.2	2	See preamble text	\$ 2.13
		SM016	eye shield, splash protection	NF		0.2	1	See preamble text	\$ 1.18
88160	Cytopath smear other source	EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	\$ (0.33)

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
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18
		EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
88161	Cytopath smear other source	L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute	0.5	0	Indirect Practice	\$ (0.18)

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
					specimen containers and or slides with requisition forms.			Expense input and/or not individually allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18
88162	Cytopath smear other source	EP038	solvent recycling system	NF		2	0	See preamble text	\$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	\$ (0.18)

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
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	\$ 0.18

TABLE 17: CY 2016 Interim Final Codes With Direct PE Input Recommendations Accepted Without Refinements

HCPCS code	Description
26356	Repair finger/hand tendon
26357	Repair finger/hand tendon
26358	Repair/graft hand tendon
43210	Egd esophagogastrc fndoplsty
47543	Endoluminal bx biliary tree
55866	Laparo radical prostatectomy
64461	Pvb thoracic single inj site
64462	Pvb thoracic 2nd+ inj site
64463	Pvb thoracic cont infusion
64566	Neuroeltrd stim post tibial
65778	Cover eye w/membrane
65780	Ocular reconst transplant
65855	Trabeculoplasty laser surg
66172	Incision of eye
67107	Repair detached retina
67108	Repair detached retina
67227	Dstrj extensive retinopathy
72170	X-ray exam of pelvis
73501	X-ray exam hip uni 1 view
73502	X-ray exam hip uni 2-3 views
73503	X-ray exam hip uni 4/> views
73521	X-ray exam hips bi 2 views
73522	X-ray exam hips bi 3-4 views
73551	X-ray exam of femur 1
73552	X-ray exam of femur 2/>
74712	Mri fetal snl/1st gestation
74713	Mri fetal ea addl gestation
77778	Apply interstit radiat compl
77790	Radiation handling
88104	Cytopath fl nongyn smears
91200	Liver elastography
93050	Art pressure waveform analys
95971	Analyze neurostim simple
95972	Analyze neurostim complex
G0416	Prostate biopsy, any mthd

TABLE 18: Invoices Received for New Direct PE Inputs for CY 2016 Interim Final Codes

CPT/HCPCS S codes	Item name	CMS Code	Average Price	No. of invoices	Estimated Non- Facility allowed services for HCPCS codes using this item
41530, 43229, 43270	radiofrequency generator (Gyrus ENT G3 workstation)	EQ374	\$ 10,000.00	1	2,932
47534, 47535, 47536, 47538, 47539, 47540	internal/external biliary catheter	SD312	\$ 162.80	1	220
47538, 47539, 47540	Viabil covered biliary stent	SD313	\$ 2,721.00	2	26
47543	Radial Jaw	SD314	\$ 94.20	1	0
47543	stone basket	SD315	\$ 417.00	1	0
64463	Catheter securement device	SD316	\$ -	0	514
76377	computer workstation, 3D reconstruction CT-MR	ED014	\$ 45,926.00	1	67,296
77778	Applicator (TPV - 200) / Kit	EQ373	\$ 9,770.00	1	517
77778	reentrant well ionization chamber	EP117	\$ 5,180.00	2	517
77778, 77790	L-block (needle loading shield)	EP118	\$ 1,195.00	1	1,848
78264, 78265, 78266	Bread	SK121	\$ 0.16	1	9,735
78264, 78265, 78266	Egg Whites	SK122	\$ 0.16	1	9,735
78264, 78265, 78266	Jelly	SK123	\$ 0.06	1	9,735
78264, 78265, 78266	paper plate	SK124	\$ 0.17	1	9,735
93050	Central Blood Pressure Monitoring Equipment (XCEL PWA & PWV System)	EP119	\$ 14,700.00	2	25,000

TABLE 19: Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item name	CMS Code	Current Price	Updated Price	% Change	Estimate d Non- Facility allowed services for HCPCS codes using this item
10035, 10036, 19081, 19082, 19083, 19084, 19085, 19086, 19285, 19286, 19287, 19288	clip, tissue marker	SD037	\$75.00	\$98.20	31%	58,640
20982, 32998, 50592, 64600, 64605, 64610, 64633, 64634, 64635, 64636	radiofrequency generator (NEURO)	EQ214	\$ 10,000.00	\$32,900.00	229%	262,846
65778	human amniotic membrane allograft mounted on a non- absorbable self-retaining ring	SD248	\$895.00	\$949.00	6%	8,807
65779	human amniotic membrane allograft	SD247	\$595.00	\$670.00	13%	104
88106	Millipore filter	SL502	\$4.15	\$0.75	-82%	1,204
95018	benzylpenicilloyl polylysine (eg, PrePen) 0.25ml uou	SH103	\$83.00	86.00	4%	60,683

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

The RUC recommended a work RVU of 10.03 for CPT code 26356. Although the RUC-recommended work RVU represents a reduction from the current work RVU of 10.62, we

believe that the decrease in resource costs as reflected in the survey data (specifically in the intraservice time, the total time, and the change in the office visits) are not adequately reflected in the recommended work RVU. The intraservice time decreased from 90 minutes to 60 minutes (33 percent) while the RUC-recommended work RVU decreased from 10.62 to 10.03, a reduction of less than 6 percent. The total time and the number of office visits were also reduced by about 25 percent in each case, which is significantly greater than the 6 percent decrease in the recommended work RVU. We examined CPT code 25607 (Open treatment of distal radial extra-articular fracture), which has an intraservice time of 60 minutes and a total time of 275 minutes, which closely approximates the 60 minutes and 277 minutes reflected in the survey results for CPT code 26356. We also believe that these procedures have similar intensity based on their clinical profiles. We are therefore establishing an interim final work RVU of 9.56 for CPT code 26356 after considering both its similarity in time to CPT code 25607 and the reduction in time relative to the current times included for this procedure.

The RUC recommended a work RVU of 11.50 for CPT code 26357. We refined the RUC-recommended work RVU, employing a similar methodology to the one we used in valuing CPT code 26356. While we agree that the value of this code should increase from its current work RVU of 8.77, we believe that the RUC-recommended work RVU of 11.50 does not accurately reflect the change in time for this code. The RUC-recommended work RVU is an increase of 31 percent from the current work RVU of the code, while the total time increases from 256 minutes to 302 minutes, an increase of only 18 percent. The intraservice time for CPT code 26357 decreases from 89 minutes to 85 minutes, which does not suggest that a significant increase to the work RVU is accurate. Therefore, we considered CPT code 27654, (Repair, secondary, Achilles tendon, with or without graft) which has a similar intraservice time of 90 minutes, a total time of 283 minutes, a similar intensity, and a work RVU of 10.53. We are establishing an interim final work RVU of 10.53 for CPT code 26357 based on this direct

crosswalk from CPT code 27654, as we believe this work RVU better reflects the changes in time for this procedure.

The RUC recommended a work RVU of 13.10 for CPT code 26358. We do not believe that this value accurately reflects the change in the intraservice time and the total time for this code. The RUC-recommended work RVU is an increase of 40 percent over the current work RVU of 9.36, while the total time only increases from 286 minutes to 327 minutes, an increase of 14 percent, and the intraservice time only increases from 108 minutes to 110 minutes, an increase of 2 percent. We do not believe that the RUC-recommended work RVU of 13.10, which corresponds to the survey median result, accurately reflects the increase in time. In the interest of preserving relativity among the codes in this family, we are maintaining the RUC-recommended increment of 1.6 work RVUs between CPT codes 26257 and 26358. Therefore, we are establishing an interim final work RVU of 12.13 for CPT code 26358, based on an increase of 1.6 work RVUs relative to CPT code 26357.

(2) Submucosal Ablation of Tongue Base (CPT Code 41530)

In the proposed rule, we proposed CPT code 41530 as potentially misvalued based on a public nomination. The nominator stated that CPT code 41530 is misvalued because there have been changes in the direct PE inputs used in furnishing the service. In the CY 2015 PFS Final Rule (79 FR 67575), we noted that the RUC submitted PE recommendations and stated that, under our usual process, we value work and PE at the same time and would expect to receive RUC recommendations for both before we revalued this service. Subsequently, the RUC submitted recommendations for both. The RUC recommended a work RVU of 3.50 for CPT code 41530, which we are establishing as the interim final work RVU for the code. To address the concerns raised by CMS in the CY 2015 PFS Final Rule, the PE Subcommittee reviewed minor revisions submitted by the specialty society. The RUC determined that this service should not be performed in the office setting and recommended removing the nonfacility direct PE

inputs from the direct PE input database. However, 2014 Medicare claims data indicate that this service is furnished in the office setting 95 percent of the time, and that this service is frequently furnished multiple times to a beneficiary. Due to this discrepancy, we are seeking comment about the typical site of service and whether changes to the coding are needed to clarify this issue. For CY 2016, we have established interim final nonfacility direct PE inputs based on the current direct PE inputs for the code.

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

The CPT Editorial Panel established CPT code 43210 to describe trans-oral esophagogastric fundoplasty. The RUC recommended a work RVU of 9.00 for CPT code 43210. We were unable to identify CPT codes with an intraservice time of 60 minutes that have an RVU of 9.00 or greater. We were also unable to identify esophagogastroduodenoscopy (EGD) codes with an RVU of 9.00 or greater. We compared this code to CPT code 43240 (Drainage of cyst of the esophagus, stomach, and/or upper small bowel using an endoscope), which has similar total work time and a work RVU of 7.25. We believe a work RVU of 7.75, which corresponds to the 25th percentile survey result, more accurately reflects the resources used in furnishing the service. Therefore, for CY 2016 we are establishing an interim final work RVU of 7.75 for CPT code 43210. Additionally, in accordance with our established policy, as described in the CY 2012 PFS Final Rule (76 FR 73119), we removed the subsequent observation visit (99224) included in the RUC recommended value for this code and adjusted the total work time accordingly, by including the intraservice time of the inpatient hospital visit in the immediate post-service time of the code.

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

Several percutaneous biliary catheter and related image guidance procedures were identified through a misvalued code screen of codes reported together more than 75 percent of

the time. For CY 2016, the CPT Editorial Panel deleted six existing biliary catheter codes (47500, 47505, 47510, 47511, 47525, and 47530) and five related image-guidance codes (74305, 74320, 74327, 75980, and 75982) and created 14 new codes, CPT codes 47531 through 47544, to describe percutaneous biliary procedures and to bundle inherent imaging services. We are establishing the RUC recommended work RVUs as interim final for CY 2016 for all of the percutaneous biliary procedures with the exception of CPT codes 47540, 47542, 47543, and 47544.

The RUC recommended a work RVU of 12.00 for CPT code 47540 (Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)) corresponding to the survey median result. We believe that a work RVU of 10.75, which corresponds to the 25th percentile survey result, more accurately reflects the work associated with this service. The RUC used magnitude estimation to value CPT code 47540, considering reference codes CPT code 37226 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) and CPT code 37228 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty). These codes have work RVUs of 10.49 and 11.00 RVUs respectively; both less than the RUC-recommended work RVU of 12.00 for CPT code 47540. In reviewing CPT codes with 90 minutes of intraservice times and a 0-day global period, we found that the majority of codes had a work RVU of less than 12.00. As such, we believe that a work RVU of 10.75 better aligns this service with other 0 day global codes with similar intraservice times and maintains appropriate relativity among the codes in this family. We are establishing a CY 2016 interim final work RVU of 10.75 for CPT

code 47540.

The RUC recommended a work RVU of 3.28 for 47542. We believe that a work RVU of 2.50 more accurately reflects the work associated with this service. In valuing CPT code 47542, the RUC used a direct crosswalk from CPT code 37185 (Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family), which has an intraservice time of 40 minutes. We believe that a more appropriate direct crosswalk is CPT code 15116 (Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, or multiple digits) because it shares an intraservice time of 35 minutes. Therefore, we are establishing an interim final work RVU of 2.50 for CPT code 47542 for CY 2016.

The RUC recommended work RVUs of 3.51 and 4.74 for CPT codes 47543 and 47544, respectively. We do not believe the RUC-recommended work RVUs accurately reflect the work involved in furnishing these procedures. To value the work described in these procedures, we used the intraservice time ratio to identify values. We used CPT code 47542 as the base code, and calculated an intraservice time ratio by dividing the intraservice time of CPT code 47543 (43 minutes) by the intraservice time of CPT code 47542 (35 minutes); we then applied that ratio (1.228) to the interim final work RVU of 2.50 for CPT code 47542. This resulted in a work RVU of 3.07 for CPT code 47543. We used the same intraservice time ratio approach to calculate the interim final work RVU for CPT code 47544. We divided the intraservice time for CPT code 47544 (60 minutes) by the intraservice time for CPT code 47542 (35 minutes), and then applied that ratio (1.714) to the interim final work RVU of 2.50 for CPT code 47542, which results in a work RVU of 4.29. We are establishing an interim final work RVU of 3.07 for CPT code 47543 and 4.29 for CPT code 47544 for CY 2016.

We also refined a series of RUC-recommended direct PE inputs. We are replacing supply

item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. We believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter.

We are also refining the RUC-recommended malpractice crosswalks for most of the codes in this family to align with the specialty mix that furnishes these procedures; we believe that these better reflect the malpractice risk associated with these procedures. We are establishing as interim final the malpractice crosswalks listed in Table 20.

TABLE 20: MP Crosswalks for Biliary and Catheter Procedures

HCPCS Code	RUC Recommended MP Crosswalk	CMS Interim Final MP Crosswalk
47531	49450	49450
47532	49407	49407
47533	37191	47510
47534	36247	47511
47535	36247	47505
47536	49452	49452
47537	49451	47505
47538	37191	47556
47539	37226	47556
47540	37226	47556
47541	36247	47500
47542	37222	47550
47543	22515	47550
47544	37235	47630

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

The CPT Editorial Panel created CPT code 49185 (Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s)) to describe percutaneous image-guided sclerotherapy of fluid collections. These services were previously reported using CPT code 20500 (Injection of sinus tract; therapeutic (separate procedure)). To develop recommended work RVUs for CPT code 49185, the RUC

used a direct crosswalk from reference code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed), which has an intraservice time of 30 minutes and work RVU of 2.78. Although CPT code 31622 is clinically similar to CPT code 49185, we do not believe CPT code 31622 has a similar intensity to CPT code 49185. To establish the CY 2016 interim final work RVU for CPT code 49185, we instead used a direct crosswalk from CPT code 62305 (injection, radiologic supervision and interpretation), which shares an intraservice time of 30 minutes and is clinically similar, as it also includes an injection, radiologic supervision, and interpretation. We are establishing an interim final work RVU of 2.35 for CPT code 49185.

The RUC recommended including 300 ml of supply item “sclerosing solution injection” (SH062) for CPT code 49185, which is priced at \$2.29 per millimeter. The predecessor code included supply item “obupivacaine (0.25% inj (Marcaine)” (SH021)), which is priced at 25.4 cents per millimeter. We are concerned that supply item SH062 may not be used in the typical case for this procedure. We note that other CPT codes that include supply item SH062 include between 1 and 10 ml. We request that stakeholders review this supply item and provide invoices to improve the accuracy of pricing. We are also requesting information regarding the price of supply item SH062 given the significant increase in volume used in this procedure relative to other procedures.

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

We are establishing as interim final the RUC-recommended work RVUs for all three codes.

For CPT code 50706, we are replacing the RUC-recommended supply item “catheter, balloon, PTA” (SD152) with a “catheter, balloon, ureteral-GI (strictures)” (SD019) in the nonfacility setting. We believe that the latter balloon catheter, which is specifically designed for ureteral procedures, would be more typically used for these procedures than a PTA balloon

catheter. We welcome further comment regarding the appropriate catheter supply for CPT code 50706, including any objective data regarding which supply item is more typically used for these procedures.

The RUC recommended the inclusion of “room, angiography” (EL011) for this family of codes. As discussed in section II.H.d.8. of this final rule with comment period, we do not believe that an angiography room would be used in the typical case for these procedures, and are therefore replacing the recommended equipment item “room, angiography” with equipment item “room, radiographic-fluoroscopic” (EL014) for all three codes on an interim final basis. Since the predecessor procedure codes generally did not include an angiography room and we do not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we do not believe that the use of an angiography room would be typical for these procedures.

We are refining the RUC-recommended MP crosswalks for the codes in this family, as we do not believe that the source codes, which are cardiovascular services, are representative of the specialty mix that would typically furnish the genitourinary catheter procedures. Instead, we are establishing interim final MP crosswalks from codes with a specialty mix similar to the expected mix of those furnishing the services described by the new codes. We are therefore establishing the following MP crosswalks as interim final for 2016: CPT code 50606 from 50955, CPT code 50705 from 50393, and CPT code 50706 from 50395.

(7) Laparoscopic Radical Prostatectomy (CPT Code 55866)

For CPT code 55866, the RUC recommended a work RVU of 26.80. This is significantly higher than the work RVU for CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing), the key reference code selected by the specialty society’s survey participants. This reference code shares an intraservice time of 180 minutes as well as similar total time (442 minutes for CPT code 55866, relative to 448 minutes for CPT code 55840). We

believe that these codes are medically similar and would require similar work resources, and CPT code 55840 was recently reviewed in CY 2014. However, CPT code 55840 has a work RVU of 21.36 while the RUC-recommended work RVU for CPT code 55866 is 26.80. We do not believe that difference in intensity between CPT code 55840 and CPT code 55866 is significant enough to warrant the difference of 5.50 work RVUs.

In addition to CPT code 55840, we also examined CPT code 55845 as another medically similar and recently RUC-reviewed procedure. CPT code 55845 is an open procedure that involves a lymphadenectomy, while CPT code 55866 is a laparoscopic procedure without a lymphadenectomy. In the CY 2014 PFS Final Rule with Comment Period, CMS requested review of CPT codes 55845 and 55866 as potentially misvalued because the work RVU for the laparoscopic procedure (55866) was higher than for the open procedure (55845). In general, we do not believe that a laparoscopic procedure would require greater resources than the open procedure. However, the RUC-recommended work RVU for CPT code 55866 is 26.80, which is still higher than the work RVU of 25.18 for CPT code 55845. We do not believe that the rank order of these work RVUs accurately reflects the relative resources typically required to furnish these procedures, and believe that the work RVU for CPT code 55866 should be lower than that of CPT code 55845. Therefore, we are establishing an interim final work RVU of 21.36 for CPT code 55866 based on a crosswalk from CPT code 55840. We believe that this is an appropriate valuation based on the procedure time and the resources typically used to furnish the procedure.

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

The CPT Editorial Panel created three new codes to describe percutaneous intracranial endovascular intervention procedures and to bundle inherent imaging services. These services were previously reported using CPT codes 61640-61642 (Balloon dilatation of intracranial vasospasm). In establishing interim final values for these services, we are refining the RUC-recommended work RVUs for all of the codes in this family. The RUC recommended a work

RVU of 17.00 for CPT code 61645 (Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial), referencing CPT code 37231 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed) and CPT code 37182 (Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS)). We believe that CPT code 37231 is an appropriate direct crosswalk because the overall work is similar to that of CPT code 61645. Therefore, we are establishing an interim final work RVU of 15.00 for CPT code 61645. Additionally, in reviewing the work time for CPT code 61645, we noted that it includes postservice work time associated with postoperative visit CPT code 99233 (level 3 subsequent hospital care, per day). As we stated in the CY 2010 PFS proposed rule (74 FR 33557) and affirmed in the CY 2011 PFS proposed rule (75 FR 40072), we believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. We believe that we should treat the valuation of the work time in the same manner as discussed previously, that is, by valuing the intraservice time of the hospital observation care service in the immediate post service time of the 23-hour stay code being valued. Therefore, we refined the work time for CPT code 61645 by removing the 55 minutes of work time associated with CPT code 99233 (subsequent hospital care) and instead included the 30 minutes of intraservice time from CPT code 99233 in the immediate postservice time of the procedure. This reduces the total work time from 266 minutes to 241 minutes and increases the immediate post service time from 53 minutes to 83 minutes.

The RUC recommended a work RVU of 12.00 for CPT code 61650 (Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory). We believe the RUC-recommended work RVU overestimates the work involved in furnishing this procedure. To establish an interim final work RVU for CPT code

61650, we are using a direct crosswalk from CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), which shares an intraservice time of 90 minutes with similar intensity. Therefore, we are establishing an interim final work RVU of 10.00 for CPT code 61650.

For CY 2016, we are also establishing interim final work time by removing the 55 minutes total time associated with CPT code 99233 (subsequent hospital care) as recommended by the RUC and instead allocating the intraservice time of 30 minutes to the immediate postservice time of the procedure. This reduces the total time from 231 minutes to 206 minutes and the immediate post service time from 45 minutes to 75 minutes.

The RUC recommended a work RVU of 5.50 for CPT code 61651 (Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to the primary code)). We believe that a direct crosswalk from CPT code 37223 (Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)), more accurately reflects the work described by CPT code 61651. We believe that CPT code 37223 is an appropriate crosswalk because it shares intraservice time, has similar intensity, and is clinically similar to CPT code 61651. Therefore, we are establishing an interim final work RVU of 4.25 for CPT code 61651.

We have also refined the RUC-recommended malpractice crosswalks for this family of codes to align with the specialty mix that furnish the services in this family. We are establishing the following interim final malpractice crosswalks in place of the RUC-recommended

malpractice crosswalks: CPT code 37218 to CPT code 61645; and CPT code 37202 to CPT codes 61650 and 61651.

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

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. We are establishing as interim final the RUC-recommended work RVUs for CPT codes 64461 and 64462. For CPT code 64463 (Paravertebral block (PVB) (paraspinous block), thoracic continuous infusion by catheter (includes imaging guidance, when performed) the RUC recommended a work RVU of 1.90, which corresponds to the 25th percentile survey result. After considering similar injection codes with identical intra-service time and longer total times, we believe the RUC recommendation for CPT code 64463 overestimates the work involved in furnishing the service. We believe a direct crosswalk from three other injection codes which all have a work RVU of 1.81 (CPT codes 64461, 64446, and 64449) more accurately reflects the work involved in furnishing this service. Therefore, for CY 2016, we are establishing an interim final work RVU of 1.81 for CPT code 64463.

(10) Ocular Surface Membrane Placement (CPT Codes 65778 and 65779)

These services were identified through the New Technology/New Services List in February 2010. For CY 2015, the RUC's Relativity Assessment Workgroup noted there may have been diffusion in technology for these services and requested that the specialty society survey these codes for work and direct PE inputs. While we are establishing the RUC-recommended work RVUs for CPT code 65778 and 65779 as interim final, we removed the work time associated with the half-day discharge management from CPT code 65779.

(11) Ocular Reconstruction Transplant (CPT Code 65780)

The RUC identified 65780 as potentially misvalued through a misvalued code screen of 90-day global services (based on 2012 Medicare utilization data) reported at least 1,000 times per year that included more than 6 office visits. The RUC recommended a direct work RVU crosswalk from CPT code 27829 (Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed). After examining comparable codes, we believe the RUC-recommended work RVU of 8.80 for CPT code 65780 overstates the work involved in the procedures given the reduction in intraservice and total times. We believe that the ratio of the total times (230/316) applied to the work RVU (10.73) more accurately reflects the work involved in this procedure. Therefore, we are establishing an interim final work RVU of 7.81 to CPT code 65780.

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

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

The RUC recommended a work RVU of 3.00. While the RUC-recommended value represents a reduction from the CY 2015 work RVU of 3.99, we believe that significant reductions in the intraservice time, the total time, and the change in the office visits represent a more significant change in the work resources involved in furnishing the typical service. The

intraservice and total times were decreased by approximately 33 percent while the elimination of two post-operative visits (CPT code 99212) alone would reduce the overall work RVU by at least 24 percent under the reverse BBM. However, the recommended work RVU only represents a 25 percent reduction relative to the previous value. To develop an interim final work RVU for this service, we calculated an intraservice time ratio between the CY 2015 intraservice time, 15 minutes, and the RUC-recommended intraservice time, 10 minutes, and applied this ratio to the current work RVU of 3.99 to arrive at a work RVU of 2.66 for CPT code 65855. Therefore, for CY 2016, we are establishing an interim final work RVU of 2.66 for CPT code 65855.

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

The RUC identified CPT codes 66170 and 66172 as potentially misvalued through a 90-day global post-operative visits screen (services reported at least 1,000 times per year that included more than 6 office visits). We believe the RUC-recommended work RVU of 13.94 for CPT code 66170 (fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery) does not accurately account for the reductions in time. Specifically, the survey results indicated reductions of 25 percent in intraservice time and 28 percent in total time. These reductions suggest that the RUC-recommended work RVU for CPT code 66170 overstates the work involved in furnishing the service, since the recommended value only represents a reduction of approximately seven percent. We believe that applying the intraservice time ratio, as described above, to the current work RVU results in a more appropriate work RVU.

Therefore, for CY 2016, we are establishing an interim final work RVU of 11.27 for CPT code 66170.

For CPT code 66172 (fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)), the RUC recommended a work RVU of 14.81. After comparing the RUC-recommended work RVUs for this code to the work RVUs of similar codes (for example, CPT code 44900 (Incision

and drainage of appendiceal abscess, open) and CPT code 59100 (Hysterotomy, abdominal (eg, for hydatidiform mole, abortion)), we believe the RUC-recommended work RVU of 14.81 overstates the work involved in this procedure. For the same reasons and following the same valuation methodology utilized above, we applied the intraservice time ratio between the CY 2015 intraservice time and the survey intraservice time, 60/90, to the CY 2015 work RVU of 18.86. This results in a work RVU of 12.57 for CPT code 66172. Therefore, for CY 2016, we are establishing an interim final work RVU of 12.57 for CPT code 66172.

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

CPT codes 67107, 67108, 67110 and 67113 were identified as potentially misvalued through the 90-day global post-operative visit screen (either directly or indirectly as being part of the same family). The RUC recommended a work RVU of 16.00 for CPT code 67107, which corresponds to the 25th percentile survey result. While the RUC recommendation represents a 5 percent reduction from the current work RVU of 16.71, we believe the RUC recommendation still overvalues the service given the 15 percent reduction in intraservice time and 25 percent reduction in total time. Using the methodology previously described, we used the intraservice time ratio to arrive at an interim final work RVU of 14.06. We believe this value more accurately reflects the work involved in this service and is comparable to other codes that have the same global period and similar intraservice time and total time. For CY 2016, we are establishing an interim final work RVU of 14.06 for CPT code 67107.

For CPT code 67108, the RUC recommended a work RVU of 17.13 based on the 25th percentile survey result, which reflects a 25 percent reduction from the current work RVU. The survey results reflect a 53 percent reduction in intraservice time and a 42 percent reduction in total time. We believe the RUC-recommended work RVU overstates the work, given the significant reductions in intraservice time and total time and does not maintain relativity among the codes in this family. To determine the appropriate value for this code and maintain relativity

within the family, we preserved the 1.13 increment recommended by the RUC, between this code and CPT code 67107, and applied that increment to the interim final work RVU of 14.06 for CPT code 67107. Therefore, we are establishing an interim final work RVU of 15.19 for CPT code 67108.

For CPT code 67110, the RUC recommended maintaining the current work RVU of 10.25. To maintain appropriate relativity with the work RVUs established for the other services within this family, we are using the RUC-recommended -5.75 RVU differential between CPT code 67107 and CPT code 67110 to establish the CY 2016 interim final work RVU of 8.31 for CPT code 67110.

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

For CY 2016, the CPT Editorial Panel established two new codes to describe fetal MRI services, which were previously billed using CPT codes 72195 (Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)), 72196 (with contrast material(s)) and 72197 (without contrast material(s), followed by contrast material(s) and further sequences). For CY 2016, we are establishing as interim final the RUC-recommended work RVU of 3.00 for 74712. The RUC recommended a work RVU of 1.85 for add-on code 74713, with an intra-service time of 35 minutes. Based on the ratio of work to time for these codes, we believe that the add-on code should approximate the relationship between work and time in the base code; therefore, we are establishing as interim final a work RVU of 1.78 for CPT code 74713, which corresponds to the 25th percentile survey result.

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

The RUC identified CPT code 77778 (interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed) and CPT code 77790 (supervision, handling, loading of radiation source) through a misvalued code screen of codes reported together more than 75 percent of the time. After reviewing the entire code family

(CPT codes 77776, 77777, 77778, and 77790), the CPT Editorial Panel deleted the interstitial radiation source codes (CPT codes 77776 and 77777) and revised CPT code 77778 to incorporate the supervision and handling of brachytherapy sources previously reported with CPT code 77790. The RUC recommended that CPT code 77790 be valued without work, and recommended a work RVU of 8.78 for CPT code 77778. We are establishing an interim final value for CPT code 77790 without a work RVU, consistent with the RUC's recommendation.

The specialty society's survey indicated that the total service time for CPT code 77778 was 220 minutes and the median work RVU was 8.78; however, the RUC recommended a total work time of 145 minutes. In reviewing that recommendation, we cannot reconcile how the RUC determined that the same survey results that overestimated the time by over 50 percent at the same time accurately estimated the work, given that time is a component of overall work. We believe that the 25th percentile survey result is more likely to represent the typical overall work in a survey in which time is overestimated. Therefore, we are establishing an interim final work RVU of 8.00 for CPT code 77778 based on the 25th percentile survey. However, we are also seeking comment regarding the accuracy of the survey results given the significant disparity between the survey results and the considered judgment of the RUC regarding the amount of overall time required to furnish this service.

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

For CY 2016, the CPT Editorial Panel revised CPT code 78264 (gastric emptying study) to describe gastric emptying procedure, and also created two new add-on codes, CPT code 78265 (gastric emptying imaging study (eg, liquid, solid, or both); with small bowel transit up to 24 hours) and CPT code 78266 (gastric emptying study (eg, liquid, solid, or both with small bowel and colon transit for multiple days)). The RUC recommendation indicates that the base CPT code 78264 was previously used to report three distinct procedural variations. The new codes were created to describe the services in the procedures.

We are establishing as interim final the RUC-recommended work RVUs for CPT codes 78265 and 78266. However, we believe the RUC-recommended work RVU of 0.80 overstates the work involved in CPT code 78264. We note that CPT code 78264 has a higher recommended work RVU and a shorter intraservice time relative to the other codes in the family. Additionally, the CY 2016 RUC survey result showed a two minute decrease, from 12 to 10 minutes, in the intraservice time for CPT code 78264. We considered reference CPT code 78226 (Hepatobiliary system imaging, including gallbladder when present), as it shares the same intraservice time of 10 minutes and has similar intensity, and we are using a direct crosswalk from the work RVU of 0.74. We are establishing an interim final work RVU of 0.74 for CPT code 78264.

We received invoices for several new supply and equipment items for colon transit imaging services, as listed in Table 21. We have accepted the invoices for these items and added them to the direct PE input database. However, we are concerned that these invoice prices may not be reflective of the typical costs associated with the submitted supply items. We request that stakeholders review these prices and provide invoices or other information to improve the accuracy of pricing for these and other items in the direct PE database. Additionally, as discussed in section II.A of the proposed rule, 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.

(18) Liver Elastography (CPT Code 91200)

For CY 2015, we used the RUC recommendation of 0.30 RVUs and direct PE inputs without refinement to establish interim final values for CPT code 91200. For CY 2016, we received an updated RUC recommendation of 0.27 RVUs; we have established the RUC-recommended work RVU and direct PE inputs as interim final.

Comment: One commenter stated a concern about the assumption that CMS used

regarding the proportion of the total Medicare utilization furnished in nonfacility and facility settings. The commenter suggested that the assumption CMS used had a significant negative impact on the PE RVUs so drastic as to not allow for the procedure to be furnished in nonfacility settings.

Another commenter requested reconsideration for the nonfacility payment rates stating the PE RVUs for the comparison codes CPT code 76700 (Ultrasound, abdominal, real time with image documentation; complete) and CPT code 76102 (Radiologic examination, complex motion (ie, hypercycloidal) body section (eg, mastoid polytomography), other than with urography; bilateral) are significantly higher than CPT code 91200. The commenter also stated the nonfacility payment was lower than the OPSS rate while the equipment costs are the same.

Response: We note that the proportion of services in the non-facility setting versus the facility setting in our utilization has no direct impact on the development of PE RVUs for each setting. We also note that the comparison codes, CPT code 76700 and CPT code 76102 have higher work RVUs; 0.81 for 76700 and 0.58 for 76102; since work is a portion of the indirect PE allocator, the comparison codes would be expected to have higher PE RVUs. Also, the capital equipment included as a direct PE input for CPT code 76700 is more expensive and is used for twice as long. While we agree with commenters that 76102 includes similarly priced equipment to 91200, we note that this equipment is used for more than 6 times as long (104 minutes vs. 16 minutes), and the clinical labor staff time is also 6 times as long. These differences in direct PE inputs and work result in a PE RVUs for the comparison codes suggested by the commenter that are far higher than the PE RVU for 91200.

With respect to the commenter's statement about the comparison of the PFS payment amount to the OPSS payment amount, we note that OPSS payments for individual services are grouped into rates that reflect the cost of a range of services. We also note that for services newly priced under the OPSS, the APC assignment is based on that of the predecessor codes and

clinical similarity to other services. As such, the payment rates for newly priced services may not be reflective of the rates that will be assigned once claims data for these services becomes available.

As stated above, we are establishing an interim final work RVU and direct PE inputs; we will accept comments during the comment period for this final rule with comment period.

(19) Electronic Analysis of Implanted Neurostimulator (CPT Codes 95971 and 95972)

For CY 2015, the RUC reviewed CPT codes 95971 and 95972 because they were identified by the High Volume Growth Services Screen which identifies services in which Medicare utilization increased by at least 100 percent from 2006 to 2011 screen. In the CY 2015 final rule with comment period, we stated that the lack of survey data for CPT code 95973, along with the confusing descriptor language and intraservice time for CPT code 95972, suggested the need for these services to be described through revised codes. However, to facilitate more accurate payment for these services pending such revisions, we adopted the RUC-recommended intraservice time of 20 minutes and work RVU of 0.78 for CPT code 95971. For CPT code 95972, we refined the RUC-recommended work RVU of 0.90 to establish an interim final value of 0.80 and adopted the RUC-recommended intraservice time of 23 minutes.

Comment: A commenter was disappointed that CMS did not accept the RUC recommendation for CPT code 95972. The commenter stated support for the RUC's determination of the work of CPT code 95972, based on its similarity to CPT code 62370. The commenter also stated that the CMS valuation for these services was arbitrary because CMS did not fully detail its methodology. The commenter recommended that CMS adopt the RUC recommendation for CPT code 95972 and continue to use the work RVU value of 0.92 for 95973 until the RUC is able to conduct a survey of 95973 and provide an updated recommendation of the work RVU value for this code.

Response: We appreciate the commenter's feedback and will consider it in finalizing

values for these codes. We note that in the CY 2015 final rule with comment period (79 FR 67670), we described our use of the intraservice time ratio methodology to develop the work RVU for 95972. Additionally, we note that for CY 2016 the RUC recommended work RVU is the same as the work RVU CMS established in the CY 2015 final rule with comment period.

For CY 2016, the CPT Editorial Panel deleted CPT code 95973 and modified the descriptor for CPT code 95972. The RUC again reviewed CPT codes 95971 and 95972 and recommended no change to the work RVU of 0.78 with an intraservice time of 20 minutes for CPT code 95971. Because the survey for CPT code 95972 had used the older descriptor, the RUC recommended that the code be resurveyed with the correct descriptor and that the current RVU of 0.80 with an intraservice time of 23 minutes be maintained until the new survey is complete. We agree with the RUC that we should use these values for these codes on an interim final basis pending new recommendations from the RUC for the CY 2017 rule based on a new survey for CPT code 95972. We look forward to receiving recommendations from the AMA RUC, and intend to consider both codes using the most recent survey data available.

(20) Prostate Biopsy, Any Method (HCPCS Code G0416)

For CY 2014, we finalized interim final work RVUs and direct PE inputs for the surgical pathology services described by CPT codes 88300 - 88309 (Surgical Pathology, Levels I through VI). In conjunction with the revaluation of these procedures, we modified the code descriptors of G0416 through G0419 so that they described any method of prostate needle biopsy services, rather than only saturation biopsies. To simplify the coding, for CY 2014, we revised the descriptor for G0416 on an interim final basis to reflect all prostate biopsies, regardless of the number of specimens taken or the method used, and we deleted the remaining G-codes. We also maintained the existing RVUs for G0416, pending additional information, including recommendations from the RUC, about the typical resource costs associated with prostate biopsies. For CY 2016, we received and will be establishing as interim final, the RUC's

recommended direct PE inputs to use in valuing G0416. However, we also received comments suggesting that the typical number of blocks used in these services can be significantly lower than what is assumed in the RUC recommendations. Given our consideration of those comments and our anticipation of a RUC-recommended work RVU for CY 2017 rulemaking, we emphasize that we are seeking evidence of the typical batch and block size used in furnishing this service.

We also note that the RUC recommended that, for purposes of calculating overall PFS budget neutrality, we assume that more practitioners will report these services accurately in the future than did so in prior years. For purposes of calculating budget neutrality, we generally assume that the Medicare utilization data reflect the accurate reporting of PFS services in compliance with Medicare payment rules. Therefore, we did not incorporate an anticipated shift toward compliant coding as recommended by the RUC. The utilization crosswalk used in setting rates for CY 2016 is available on the CMS Web site under downloads for the CY 2016 PFS Final Rule at <http://www.cms.gov/physicianfeesched/PFSFederalRegulationNotices.html/>.

TABLE 21: Invoices Received For New Direct PE Inputs

CPT/HCPCS codes	Item name	CMS Code	Average Price	No. of invoices	Estimated Non-Facility allowed services for HCPCS codes using this item
41530, 43229, 43270	radiofrequency generator (Gyrus ENT G3 workstation)	EQ374	\$ 10,000.00	1	2,932
47534, 47535, 47536, 47538, 47539, 47540	internal/external biliary catheter	SD312	\$ 162.80	1	220
47538, 47539, 47540	Viabil covered biliary stent	SD313	\$ 2,721.00	2	26
47543	Radial Jaw	SD314	\$ 94.20	1	0

CPT/HCPCS codes	Item name	CMS Code	Average Price	No. of invoices	Estimated Non-Facility allowed services for HCPCS codes using this item
47543	stone basket	SD315	\$ 417.00	1	0
64463	Catheter securement device	SD316	\$ -	0	514
76377	computer workstation, 3D reconstruction CT-MR	ED014	\$ 45,926.00	1	67,296
77778	Applicator (TPV - 200) / Kit	EQ373	\$ 9,770.00	1	517
77778	reentrant well ionization chamber	EP117	\$ 5,180.00	2	517
77778, 77790	L-block (needle loading shield)	EP118	\$ 1,195.00	1	1,848
78264, 78265, 78266	Bread	SK121	\$ 0.16	1	9,735
78264, 78265, 78266	Egg Whites	SK122	\$ 0.16	1	9,735
78264, 78265, 78266	Jelly	SK123	\$ 0.06	1	9,735
78264, 78265, 78266	paper plate	SK124	\$ 0.17	1	9,735
93050	Central Blood Pressure Monitoring Equipment (XCEL PWA & PWV System)	EP119	\$ 14,700.00	2	25,000

I. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

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

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

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

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

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

Telephones, facsimile machines, and stand-alone electronic mail systems 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 a telehealth originating site.

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

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

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a facility fee under the PFS for each Medicare telehealth service. The statute specifies both the types of entities that can serve as originating sites and the

geographic qualifications for originating sites. With regard to geographic qualifications, §410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical area (MSA).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of 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 website tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

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

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

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

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare

telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (76 FR 73102). The two categories are:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.

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

For the list of telehealth services, see the CMS website at

<https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 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 website at

<https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

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 for the roles of,

and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, 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 found that the following services were sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category 1 basis. Therefore, we proposed to add the following services to the telehealth list on a category 1 basis for CY 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 30 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 could be furnished when a patient is located at a telehealth 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 to provide 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 did not propose to add the following procedures for the reasons noted:

- All E/M 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, based on the category 2 criteria at the time of that request. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a new request for CY 2016, 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 telemedicine significantly reduced mortality rates or hospital length of stay, we do not believe that the submitted evidence demonstrates a clinical benefit to patients. Therefore, we did not propose to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016.

- 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 did not propose to add these nonpayable 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 service 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 did not propose 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 did not propose to add these services to the list of Medicare telehealth services for CY 2016.

In summary, we proposed 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 90963 through 90966. 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 30 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, CNS, NP, or PA.

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) of the Act, which includes a certified registered nurse anesthetist (CRNA) as defined in section 1861(bb)(2) of the Act.

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 proposed 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.

The following is a summary of the comments we received on proposals related to telehealth services.

Comment: All commenters supported one or more of our proposals to add prolonged service inpatient procedures (CPT codes 99356 and 99357) and ESRD-related services for home dialysis procedures (CPT codes 90963, 90964, 90965 and 90966) to the list of Medicare telehealth services for CY 2016.

Response: We appreciate the commenters' support for the proposed additions to the list of Medicare telehealth services. After consideration of the public comments received, we are finalizing our CY 2016 proposal to add these services to the list of telehealth services for CY 2016 on a category 1 basis.

Comment: Concerning our proposal to add prolonged services in the inpatient or observation setting (CPT codes 99356 and 99357) to the telehealth list, a few commenters questioned the need for CMS to establish a limit on the frequency with which these services can be provided, since there is no such limit when they are provided in-person. The commenter suggested that the criteria should be whether the services are reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice. The commenter concluded that care provided via telemedicine should be paid as other physician services and that the technology used to deliver the services should not be the primary consideration.

Response: In the PFS final rule for CY 2011 (75 FR 73317), we concluded that subsequent hospital care visits by a patient's admitting practitioner may sufficiently resemble follow-up inpatient consultation services to add these subsequent hospital care services on a category 1 basis for the telehealth list. Although we still believed the potential acuity of hospital inpatients is greater than those patients likely to receive currently approved Medicare telehealth services, we also believed that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have frequent encounters with their admitting practitioner. However, we also believed that the majority of

these visits should be in-person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis.

Therefore, we added subsequent hospital care services, specifically CPT codes 99231, 99232, and 99233, to the list of telehealth services on a category 1 basis in CY 2011, but with some limitations on the frequency with which these services may be furnished through telehealth. Because of our concerns regarding the potential acuity of hospital inpatients, we limited the provision of subsequent hospital care services through telehealth to once every 3 days. We were confident that admitting practitioners would continue to make appropriate in-person visits to all patients who need such care during their hospitalization.

Likewise, for CY 2011, we concluded that subsequent nursing facility visits by a patient's admitting practitioner sufficiently resemble follow-up inpatient consultation services to consider them on a category 1 basis for the telehealth list. We concluded that it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, although we continued to believe that the federally mandated visits should be in-person to facilitate the comprehensive, coordinated, and personal care that these complex patients require on an ongoing basis.

Therefore, we added subsequent nursing facility care services, specifically CPT codes 99307, 99308, 99309, and 99310, to the list of Medicare telehealth services on a category 1 basis in CY 2011, with some limitations on furnishing these services through telehealth. Because of our concerns regarding the potential acuity and complexity of SNF inpatients, we limited the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We believe the concerns that we addressed in the cases discussed in this section continues to hold for CPT codes 99356 and 99357, and that frequency limits are appropriate to ensure that

patients continue to receive appropriate and high-quality care.

We note that section 1834(m) of the Act requires Medicare to make the same payment for services furnished via telehealth as is made for face-to-face services. In addition, it provides for payment of an originating site facility fee. However, the statute does not require that all conditions for payment for telehealth services be the same as for the services when furnished without the use of an interactive telecommunications system. We continue to believe the established frequency limits are appropriate and will leave them in place for these services.

Comment: Some commenters supported and others disagreed with our decision not to add critical care services (CPT codes 99291 and 99292) to the list of telehealth services. One commenter questioned why intensive care unit (ICU) telemedicine (TM) must demonstrate significantly reduced mortality rates or hospital length of stay for Medicare coverage. The commenter further noted that CMS covers new codes and procedures routinely without any evidence that they significantly reduce mortality rates or hospital length of stay. The commenter suggested that the criteria should be whether the proposed telehealth services are reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice. The commenter believes CMS is applying a comparative effectiveness standard to coverage of telehealth services that it does not apply elsewhere in its coverage and payment for physician services, resulting in a double standard for coverage.

Another commenter questioned our statement that there is “no evidence that the implementation of ICU TM significantly reduce[s] mortality rates or hospital length of stay,” noting that these are not category 2 criteria and that telemedicine for critical care services clearly meets the following three criteria for adding services on a category 2 basis:

- 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.

The commenter maintained that telemedicine is safe and feasible for all patients. The commenter further maintained that advances in today's technology enable health care providers to deliver a focused, critical intervention no matter where the patient may be situated and/or what services are delivered.

Another commenter questioned the relevance of the "JAMA Internal Medicine Study" we cited because it involved VA hospitals whose patients do not represent the Medicare patient population. Finally, a commenter indicated that adding these services to the telehealth list would support the clinical stabilization of such patients awaiting critical care and/or surgical intervention or transport, in which a specialist may not be available to support the immediate clinical needs of the patient.

Response: We disagree that we have applied a comparative effectiveness standard to the coverage of telehealth. As noted, in reviewing requests to add services on a category 2 basis, we look for evidence indicating that the use of a telecommunications system in furnishing the candidate telehealth service produces clinical benefit to the patient. In this circumstance of ICU critical care, we did not review the evidence to determine if the evidence demonstrated that the benefit of in-person ICU critical care was greater than in a telemedicine setting. We limited our review to the evidence of benefit of telemedicine in ICU critical care.

As noted in the proposed rule (80 FR 41783), we reviewed the information provided by the ATA. We also reviewed 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 that addressed potential clinical benefits of these kinds of services furnished via telehealth. The two studies had contradictory conclusions. In any evidentiary

review, valid conclusions must be made based upon the totality of the available evidence. One must look at the quality of the study, the study hypothesis, appropriate study design, appropriate inclusion/exclusion factors, appropriate statistical analyses, and many other factors to adequately address the validity of the data. These factors are then used to draw conclusions about the totality of the evidence. In doing so for this service, we concluded that the totality of the evidence did not demonstrate a benefit for ICU telemedicine. This conclusion does not mean that a benefit does not exist. This conclusion only states that the totality of the evidence is not sufficient to reach a conclusion that a benefit exists. Although our proposal not to add these codes to the telehealth list did not specifically address whether or not the critical care service is accurately described by the requested codes when furnished via telehealth, we also reconsidered that portion of the category 2 criteria when we reconsidered our assessment in the context of the comments on the proposed rule. Based on our review of the code descriptors and CPT prefatory language, we do not believe that the services described by the critical care codes accurately describe the full range of services required by patients in need of that level of care. Instead, we believe that the kinds of services furnished to these patients via telehealth are more accurately described by the inpatient/emergency department telehealth consultation codes, which are already on the list of Medicare telehealth services. Specifically, we believe that the kinds of telehealth services commenters describe as effective in the clinical stabilization of patients awaiting critical care and/or surgical intervention or transport, and in which a specialist may not be available to support the immediate clinical needs of the patient, are more accurately described and paid through the telehealth g-codes than through the critical care E/M CPT codes that describe in-person services.

In response to commenters who suggested that we are applying a “double standard” for coverage of telehealth services, we note that section 1834(m)(4)(F) of the Act initially provided a payment mechanism for services furnished via telehealth for professional consultations, office

visits, and office psychiatry services. The statute further required the Secretary to establish a process for annual additions or deletions to the telehealth list to be paid under particular circumstances. The statute does not suggest that any service that potentially could be furnished via telehealth should be included. Rather, the statute specifies a consideration process by CMS before making changes to the list of Medicare telehealth services. Since establishing the process in 2002, we have added codes to the telehealth list on a regular basis and we will continue to do so, as appropriate, using the established process.

Comment: A few commenters objected to our decision not to add online E/M service, chronic care management services, and medication therapy management services to the telehealth services list.

Response: As noted, online E/M service (CPT code 99444) is currently noncovered; there would be no Medicare payment if this service was furnished without the use of a telecommunications system. Chronic care management services (CPT code 99490) can be furnished without the beneficiary's face-to-face presence and using any number of non-face-to-face means of communication. Therefore, it is unnecessary to add this service to the list of Medicare telehealth services. The chronic care management service can inherently be furnished using a wide range of remote communication technologies. Medication therapy management services (CPT codes 99605-99607) are noncovered services for which no payment may be made under the PFS. Therefore, we did not propose to add these services to the list of Medicare telehealth services for CY 2016.

Comment: Concerning our decision to add ESRD services (CPT codes 90963 through 90764) which includes counseling of parents, a commenter requested adding counseling of caregiver and family as all patients may not have parents as their only caregiver.

Response: Although the CPT code descriptor specifies only parents, we believe that legal guardians would be recognized in lieu of parents.

Comment: Commenters requested that:

- A patient's home, a dialysis facility, and an assisted living facility serve as originating sites for telehealth services.

- Originating site restrictions to rural areas be eliminated.

- Home health providers, registered nurses (RNs), Certified Pediatric Nurse Practitioners (CPNPs) and Certified Family Nurse Practitioners (CFNPs) be included in the list of eligible providers telehealth.

- The ability of NPs and PAs in a retail clinic setting to furnish telehealth services be clarified and that payment be commensurate with furnishing an in-person service.

Response: Section 1834(m)(4)(C) of the Act does not include a patient's home, a dialysis facility, or an assisted living facility as an originating site. Additionally, an originating site must be in a rural HPSA; in a county that is not in an MSA; or a participant in a federal telemedicine demonstration project approved as of December 31, 2000.

Section 1834(m)(4)(E) of the Act defines a practitioner for telehealth services per section 1842(b)(18)(C), which does not include home health providers or RNs. CPNPs or CFNPs are authorized to furnish telehealth services if they meet the conditions for NPs in section 1861(a)(a)(5) of the Act. NPs and PAs can furnish telehealth service as distant site practitioners. There are no specific criteria for a distant site. Therefore, there are no telehealth rules that would prohibit eligible distant site practitioners from furnishing telehealth services from a retail clinic, assuming the telehealth individual (beneficiary) is located at a telehealth originating site. Section 1834(m)(2)(A) of the Act provides that payment for a service furnished via telehealth equals the payment that would be made for an in-person service. Because these requirements are specified in the statute, we do not have discretion to revise the telehealth rules as desired by the commenters.

Comment: Many commenters supported, and one commenter opposed, our proposal to revise §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. One commenter expressed concern that CRNAs furnish only services they are qualified to furnish.

Response: We appreciate the commenters' support for the proposal to revise the regulation. We note that section 1834(m)(4)(E) of the Act defines a practitioner for telehealth services per section 1842((b)(18)(C) of the Act, which includes CRNAs. We also note that CRNAs can only furnish services they are legally authorized to perform in the state in which the services are performed. After consideration of the public comments received, we are finalizing our proposal to revise §410.78(b)(2) to include a CRNA.

We wish to inform stakeholders of the following initiatives to promote telehealth:

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models to lower costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. As part of that authority, the CMS Innovation Center can consider potential new payment and service delivery models to test changes to Medicare's telehealth payment policies. For example, the Next Generation Accountable Care Organization (ACO) Model is an Innovation Center initiative for ACOs that are experienced in coordinating care for populations of patients. It will allow these provider groups to assume higher levels of financial risk and reward than are available under the current Pioneer ACO Model and Medicare Shared Savings Program (Shared Savings Program). The goal of the Model is to test whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes and lower expenditures for Medicare fee-for-service (FFS) beneficiaries. Central to the Next Generation ACO Model are several benefit enhancement tools to help ACOs improve engagement with beneficiaries. ACOs participating in this Model have the opportunity to provide aligned beneficiaries with access to home visits and

telehealth services that exceed what is currently covered under the Medicare program, and CMS will make reward payments to aligned beneficiaries who receive a high percentage of their care from the ACO and from certain providers and suppliers that have agreed to participate in the ACO's network as ACO Participants or Preferred Providers under this Model.

The Fed-Tel Committee is comprised of employees from various federal agencies whose purpose is to facilitate telehealth education and information sharing, as well as coordinate funding opportunity announcements and other programmatic materials.

We reminded 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 website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31 2002, at \$20.00. For telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2016 is 1.1 percent. Therefore, for CY 2016, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or \$25.10. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 22.

TABLE 22: The Medicare Telehealth Originating Site Facility Fee and MEI Increase by the Applicable Time Period

Time Period	MEI Increase	Facility Fee
10/01/2001–12/31/2002	N/A	\$20.00
01/01/2003–12/31/2003	3	\$20.60
01/01/2004–12/31/2004	2.9	\$21.20
01/01/2005–12/31/2005	3.0	\$21.86
01/01/2006–12/31/2006	2.8	\$22.47
01/01/2007–12/31/2007	2.1	\$22.94
01/01/2008–12/31/2008	1.8	\$23.35
01/01/2009–12/31/2009	1.6	\$23.72
01/01/2010–12/31/2010	1.2	\$24.00
01/01/2011–12/31/2011	0.4	\$24.10
01/01/2012–12/31/2012	0.6	\$24.24
01/01/2013–12/31/2013	0.8	\$24.43
01/01/2014–12/31/2014	0.8	\$24.63
01/01/2015–12/31/2015	0.8	\$24.83
01/01/2016–12/31/2016	1.1	\$25.10

J. 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, the regulation at §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 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 supervision (as specified under §410.26(a)(2) and §410.26(b)(5)) 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) (PAs’ services), §410.75(d) (NPs’ services), §410.76(d) (CNSs’ services), and §410.77(c) (certified nurse-midwives’ services). 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, when referring in this discussion 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 final rule with comment period, 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)) with the exception that allows care management services and transitional care management services (other than the required face-to-face visit) to be furnished under the general supervision of the physician (or other practitioner.)

We proposed 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 (66 FR 55267), in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, 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. Additionally, in Transmittal 148, which was published on April 23, 2004, effective May 24, 2004, we specifically instructed practitioners as to how claim forms should be completed to account for the fact that the supervising physician or other practitioner is responsible for the incident to service. 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 proposed to amend §410.26(b)(5), consistent with previous preamble discussion and subregulatory guidance, 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 proposed to remove the last sentence from §410.26(b)(5), which specified 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. We proposed 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 (OIG) 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 being inadvertently deemed non-compliant. Therefore, while we believe that the initial responsibility of compliance rests with the

practitioner, we invited comments through this final rule with comment period about possible approaches we could take to improve our ability to ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations. We invited commenters to consider the options we considered, 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 considered these comments in the course of finalizing proposals for CY 2016, and will continue to consider these comments should 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.

The following is a summary of the comments we received regarding our proposals on “incident to” services.

Comment: Many commenters sought clarification on whether CMS’s proposal requires that a physician or other practitioner who furnishes the initial care and/or orders or refers incident to services must also be the same individual who also directly supervises and bills Medicare for incident to services. These commenters urged CMS to clarify that the proposed change would not require that the physician or other practitioner who orders, refers, develops a treatment plan, or initiates treatment must also directly supervise all incident to services.

Response: We understand these comments, and in making our proposal, we intended to amend the current incident to regulations to state explicitly that only the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services may bill Medicare for the incident to services. The proposed policy was not intended to require that the supervising physician or other practitioner must be the same individual as the physician

or other practitioner who orders or refers the beneficiary for the services, or who initiates treatment. Rather, we intended to clarify that under circumstances where the supervising practitioner is not the same as the referring, ordering, or treating practitioner, only the supervising practitioner may bill Medicare for the incident to service. As stated in the CY 2002 PFS final rule at 66 FR 55267 in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, we stated that 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. When the billing number of the physician or other practitioner is reported on the claim form, the physician or practitioner is stating that he or she directly performed the service, or supervised the auxiliary personnel performing the service consistent with the required level of supervision. Accordingly, we believe that an explicit statement in the regulations text further strengthens our intent that only the physician or other practitioner directly supervising the incident to services may bill Medicare for the incident to services.

Comment: While some commenters supported our proposal to amend regulatory text regarding incident to services, the majority of commenters opposed our proposal to remove the last sentence from §410.26(b)(5) to clarify our proposal to require that the billing physician or other practitioner for incident to services must have directly supervised the auxiliary personnel who provided incident to services. This sentence in the current incident to regulations 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. Most of these commenters believe that the removal of this sentence represents a change in longstanding policy regarding how incident to services are furnished and billed, especially by group practices and multispecialty clinics, rather than a clarification about who the program requires to bill for incident to services. Other commenters stated that we should maintain the

final sentence of §410.26(b)(5), in current regulations because they believe the policy, as expressed in the sentence allows for situations where incident to services may be furnished during an extended course of care under the supervision of a different physician or other practitioner than the one that is ordering, referring, diagnosing, or initially treating the patient. Still other commenters suggested that our proposal to remove the sentence will severely impact patient care in terms of access, creating delays in care and in some cases restricting care for patients -- particularly those in rural areas and low-income populations, when the same physician or other practitioner who orders services and/or initiates care is not also available and present to directly supervise the incident to services. Additionally, many of these commenters urged us to restore the sentence that we proposed to remove, or to not finalize the proposal, because they believe it would be overly burdensome to group practices and multispecialty clinics to impose the proposed billing and supervision requirements. These commenters indicated that, for these types of practices or for anything other than a solo practice, our proposal creates a financial burden, requires extensive restructuring, and imposes operational and staff coverage difficulties particularly in locum tenens situations, scheduling vacations and, in situations where the same physician or other practitioner does not practice daily at the same location.

Response: We appreciate the concerns of commenters who urged us not to delete the final sentence in regulation at §410.26(b)(5). Since we believe the incident to services provided by auxiliary personnel are based on the professional services of the directly supervising physician or other practitioner (who has a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment), we thought our regulations would be made clearer by removing the final sentence of the regulation at §410.26(b)(5). We have considered the extensive and insightful comments expressing concern about how the removal of the subject sentence might be construed to be a change in policy that would require that the physician (or other practitioner) supervising the auxiliary personnel must be the same physician

(or other practitioner) who is treating the patient more generally. We also considered the comments from stakeholders who suggested the change in the regulatory language would adversely impact the physician community, particularly group practices and multispecialty clinics. Given the concerns that have been expressed, we are not finalizing our proposal to delete the final sentence of the regulatory language. Instead, we will revise this sentence to reflect our policy that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) treating the patient more broadly. In addition to this revised sentence, we will add clarifying regulation text specifying that only the physician or other practitioner under whose supervision the incident to service(s) are being provided is permitted to bill the Medicare program for the incident to services.

Comment: One commenter disagreed with our proposal to specify that only the directly supervising physician or other practitioner is permitted to bill for incident to services. The commenter advised that, in single specialty groups, to require that incident to services must be billed by the directly supervising physician or other practitioner who is present at the time the incident to services are furnished, rather than the ordering physician or other practitioner who is also present, creates an unnecessary tracking, accounting, and scheduling burden on the practice. The commenter suggested that in situations where the ordering physician or other practitioner and the directly supervising physician or other practitioner are in the same single specialty group, and both are present at the time that auxiliary personnel are providing incident to services, either the ordering or supervising physician or other practitioner should be permitted to bill for the incident to services.

Response: Although the physician or practitioner who orders or refers a beneficiary for a service has a connection to the services, we believe the physician or other practitioner directly supervising the incident to service assumes responsibility and accountability for the care of the patient that is provided by auxiliary personnel. Hence, we maintain that it is appropriate to limit

billing for incident to services to the physician or practitioner who supervises the provision of those services. Although we understand that individual practitioners or practices may need to improve the tracking and accounting regarding the supervision and billing of incident to services, we do not agree with the commenter that such tracking or accounting is unnecessary. Instead, we believe that such tracking and accounting is necessary to ensure that practitioners bill appropriately for services furnished incident to their professional services.

Comment: Some commenters supported our proposal to amend the current regulations to state explicitly that only the directly supervising physician or other practitioner can bill the program for incident to services, and to remove the sentence under current regulations indicating that the physician or other practitioner directly supervising the auxiliary personnel need not be the same physician or other practitioner upon whose professional service the incident to service is based. These commenters interpreted our proposal to promote clear direction on the appropriate billing practices for incident to services in that the proposals are transparent and impose accountability. Additionally, one of these commenters characterized our proposals as clarifications that will allow small primary care practices to continue providing high quality and coordinated care.

Response: We appreciate these comments, which indicate that the commenters understood the intent of our proposals and did not interpret them as requiring changes in the way incident to services are furnished and billed.

Comment: Most commenters that addressed our proposal regarding auxiliary personnel who have been excluded or revoked from the Medicare program supported our approach. The commenters stated that since excluded or revoked individuals are already prohibited from furnishing incident to services to Medicare patients, our proposal will 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 program requirements. The commenters

believe that our proposed prohibition will improve the quality of incident to services overall because it offers an additional safeguard against the possibility of auxiliary personnel who have been excluded or revoked from the Medicare program continuing to provide services to beneficiaries by obscuring them as incident to the services of another practitioner. However, one commenter opposed the proposal because the commenter believed that it would prevent marriage and family therapists from providing incident to services as auxiliary personnel since the commenter believed these therapists are excluded from the Medicare program.

Response: We appreciate the support for our proposal and are finalizing our proposal. We clarify that the term “excluded” in this context does not refer to the kinds of practitioners who do not have a benefit, and are not permitted to bill independently for their services under Medicare law.

Comment: In addition to the comments discussed above that are specifically related to our proposals, we received several comments in response to our solicitation of comments regarding future potential compliance and oversight considerations for incident to services. We also received several comments on the incident to benefit that are outside the scope of our specific proposal or solicitation. These comments addressed issues such as: developing a list of CPT codes to distinguish therapeutic services that can be billed on an incident to basis from diagnostic tests that cannot be billed incident to; an explicit determination about whether CPT codes representing services that contain both a technical component and a professional component can be billed incident to; or whether CPT codes representing services with only a technical component can be billed incident to; and how transition care management and chronic care management services are affected by incident to requirements.

Response: We thank commenters for their feedback. We will consider these comments in the context of developing future improvements to guidance regarding incident to services.

After considering the comments that we received on incident to services under our

proposed rule, we are finalizing the changes to our regulation at §410.26(a)(1) without modification, and we are finalizing the proposed change to the regulation at §410.26(b)(5) with a clarifying modification. Specifically, we are amending the definition of the term, “auxiliary personnel” at §410.26(a)(1) that are permitted to provide “incident to” services to exclude individuals who have been excluded from the Medicare program or have had their Medicare enrollment revoked. Additionally, we are amending §410.26(b)(5) by revising the final sentence to make clear that the physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) that is treating the patient more broadly, and adding a sentence to specify that only the physician (or other practitioner) that supervises the auxiliary personnel that provide incident to services may bill Medicare Part B for those incident to services.

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

Part B's payment to portable X-ray suppliers includes 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 during the course of the visit, the portable X-ray transportation fee is prorated to reflect this. We have received feedback that some portable X-ray suppliers have been operating under the assumption that when multiple patients receive portable X-ray services in this manner, the transportation fee would only be prorated among a subset of those 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 determine the transportation fee attributable to Medicare Part B by allocating it among all patients who receive portable X-ray services in a single trip. Medicare Part B should not pay for more than its share of the transportation costs for portable X-ray services.

For CY 2016, we proposed 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 also proposed to clarify that this subregulatory guidance means that, when more than one patient is X-rayed at the same location, the transportation payment under the PFS for the Part B patient(s) is to be prorated by allocating the trip 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 during a single trip to a skilled nursing facility (SNF), we believe that the transportation fee should be allocated among all patients receiving services during the trip, irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. Thus, for a Medicare Part B patient, the prorated transportation fee made under Part B would appropriately reflect the share of the trip that is actually attributable to that patient. The following is a summary of the comments we received on our proposal to clarify the subregulatory guidelines to determine Medicare Part B's portion of the portable X-ray services' transportation fee.

Comment: Some commenters supported our proposal to clarify the current subregulatory guidance for the portable X-ray transportation fee. The commenters believe that this proposal will ensure consistent treatment of the payment for transportation among the different MACs and will eliminate the overpayment of portable X-ray transportation services. Other commenters supported our proposal, but advised CMS not to implement the proposal without also including a transportation fee proration policy for payers under Medicare Part A, Medicare Advantage, and Medicaid to pay an amount for transportation that is equal to the proportion of their covered patients receiving an X-ray on that trip to the facility. If CMS implements the proration of the transportation fee for Medicare Part B only, the commenters stated that the result will be reduced payment to the portable X-ray transportation suppliers.

Response: We appreciate the commenters' support for our proposal. With regard to the commenters that asked CMS to consider requiring Medicare Part A and non-Medicare payers to pay a prorated transportation fee amount for their covered patients receiving portable X-ray services during the same trip, we note that such requirements generally are beyond the scope of this rule. However, with regard to payment under Medicare Part A, as we noted in the SNF prospective payment system (PPS) final rule for CY 2016 (80 FR 46408, August 4, 2015), under

the SNF PPS, a SNF's global per diem payment for its resident's covered Part A stay specifically includes the portable X-ray's transportation and setup. Further guidance on arrangements between SNFs and their suppliers is contained in CY 2016 SNF prospective payment system (PPS) final rule with comment period, which is available online at <http://www.gpo.gov/fdsys/pkg/FR-2015-08-04/pdf/2015-18950.pdf>.

Comment: Another commenter disagreed with the proposal and indicated that the proration among Part B patients may discourage community-based services if portable X-ray suppliers reduce their services in light of the potential reduction in the payment they previously received for the transportation fee. The commenter is concerned that if portable X-ray suppliers do not provide X-ray services in SNFs or other places where Medicare Part B beneficiaries reside, that the beneficiaries would be required to receive X-ray services in a hospital or other facility. The commenter suggested CMS consider the negative impact of the proposal in the context of the improved care and lowered cost of services in the community as compared to facility-based care. The commenter also expressed concern about how this would affect non-Medicare patients since third party payers often end up paying more to offset reduced Medicare payments levels.

Response: We appreciate the commenter's feedback, and understand the concerns raised regarding the implications of our proposal. We agree that Medicare payment for services should encourage access to care for Medicare beneficiaries. However, we do not believe that the consistent application of payment policies that permit Medicare Part B to make payment only for costs attributable to services furnished to Medicare Part B patients is likely to discourage community-based care such as portable X-ray services provided to individuals residing in a SNF.

After consideration of the comments we received, we are finalizing our proposed change to the subregulatory guidance in the Medicare Claims Processing Manual (Pub. 100-4, Chapter 13, Section 90.3) to clarify the portable X-ray transportation fee proration policy, effective

January 1, 2016. We believe the revision to the Manual provides consistent direction to all MACs in the payment of portable X-ray transportation for Medicare Part B claims. In addition, we believe the revision strengthens program integrity under Medicare Part B because Medicare will no longer pay for more than its share of the portable X-ray transportation costs.

We received several comments that are not within the scope of our proposal to clarify the subregulatory guidance in §90.3 of the Medicare Claims Processing Manual, which pertains to portable X-ray transportation fee proration policy. The topics addressed by commenters included recommendations that CMS:

- Update regulations which govern conditions for coverage of portable x-ray services.
- Consider allowing certain services to be performed in a mobile setting.
- Clarify and/or change the consolidated billing payment policy of diagnostic tests

including portable X-ray.

- Use multiple transportation codes that describe costs attributable to different imaging modalities.

Response: We appreciate these comments, but they are beyond the scope of this rule. However, we will review all recommendations provided and consider them in the development of future policy.

L. 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 §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)) 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. Although we modified the definition of colorectal cancer screening services in §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 proposed a technical correction to amend §410.160(b)(8) to expressly recognize anesthesia services. Specifically, we proposed 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.

Comment: A few commenters thanked us for modifying the definition of colorectal cancer screening services to include anesthesia care and for making the conforming change to regulations, noting that this will help to increase access to screening colonoscopies. The commenters also stated that the coinsurance should be waived in instances where the screening becomes diagnostic, but noted that they understand that CMS may not have the statutory authority to make this change. Commenters also stated that if CMS were to receive such authority, they hope CMS would make the associated regulatory change as quickly as possible so that beneficiaries would be further encouraged to seek the screening.

One commenter urged CMS to identify a way a way under the existing authority to redefine colorectal cancer screening to include colonoscopy with removal of polyp or abnormal growth during the screening encounter. The commenter stated that nearly half of all patients who undergo screening colonoscopy have a polyp or other tissue removed, and believed that the current policy is unfair and disproportionately affects lower income beneficiaries. The commenter also stated that there are various types of colorectal cancer screenings, including fecal occult blood test, double contrast barium enema, and CT colonography, and urged CMS to cover these other screening tests without cost-sharing obligations for the beneficiary.

Response: We thank the commenters for their feedback and will consider the issues that are within our authority for future rulemaking. After consideration of these comments, we are

finalizing our proposed technical correction to amend §410.160(b)(8).

M. Therapy Caps

1. Outpatient Therapy Caps for CY 2016

Section 1833(g) of the Act requires application of annual per beneficiary limitations on the amount of expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as “therapy caps.” There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

The therapy caps apply to outpatient therapy services furnished in all settings, including the previously exempted hospital setting (effective October 1, 2012) and critical access hospitals (CAHs) (effective January 1, 2014).

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year’s cap by the MEI for the upcoming calendar year and rounding to the nearest \$10.00. Increasing the CY 2015 therapy cap of \$1,940 by the CY 2016 MEI of 1.1 percent and rounding to the nearest \$10.00 results in a CY 2016 therapy cap amount of \$1,960.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended multiple times through subsequent legislation as described in the CY 2015 PFS final rule with comment period (79 FR 67730) and most recently extended by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). The Agency’s current authority to provide an exceptions process for therapy caps expires on December 31, 2017.

CMS tracks each beneficiary’s incurred expenses annually and counts them towards the therapy caps by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount. As required by section 1833(g)(6)(B), added by section

603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) and extended by subsequent legislation, the PFS-rate accrual process is applied to outpatient therapy services furnished by CAHs even though they are paid on a cost basis. After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the therapy caps, therapy suppliers and providers use the KX modifier on claims for subsequent services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record. Claims for outpatient therapy services over the caps without the KX modifier are denied.

Since October 1, 2012, under section 1833(g)(5)(C) of the Act, we have been required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses for outpatient therapy services exceed a threshold amount of \$3,700. There are two separate thresholds of \$3,700, just as there are two separate therapy caps, one for OT services and one for PT and SLP services combined; and incurred expenses are counted towards the thresholds in the same manner as the caps. Now, under section 1833(g)(5) of the Act as amended by section 202(b) of the MACRA, claims exceeding the therapy thresholds are no longer automatically subject to a manual medical review process as they were before. Rather, CMS is permitted to do a more targeted medical review on these claims using factors specified in section 1833(g)(5)(E)(ii) of the Act as amended by section 202(b) of the MACRA, including targeting those therapy providers with a high claims denial rate for therapy services or with aberrant billing practices compared to their peers. The statutorily-required manual medical review process required under section 1833(g)(5)(C) of the Act expires at the same time as the exceptions process for therapy caps on December 31, 2017.

For information on the manual medical review process, go to

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html>.

2. Applying Therapy Caps to Maryland Hospitals.

Since October 1, 2012, the therapy caps and related provisions have applied to the outpatient therapy services furnished by hospitals as recognized under section 1833(a)(8)(B) of the Act. Before then, outpatient therapy services furnished by hospitals had been exempted from the statutory therapy caps. Since 1999, hospitals have been paid for the outpatient therapy services they furnish at PFS rates – the applicable fee schedule established under section 1834(k)(3) of the Act.

Beginning October 1, 2012, CMS has been required to apply the therapy caps and related provisions to outpatient therapy services under section 1833(g) of the Act furnished in hospitals. As with other statutory provisions on therapy caps, this provision has been extended several times by additional legislation. Most recently, section 202(a) of the MACRA extended this broadened application of the therapy caps to include outpatient therapy services furnished by hospitals through December 31, 2017.

When we first implemented the statutory provision that extended application of the therapy caps to outpatient therapy services furnished by hospitals, we did not apply the therapy caps to most hospitals in Maryland. Originally, this omission was linked to our longstanding waiver policy under section 1814(b) of the Act, which allowed Maryland to set the payment rates for hospital services, including those for the outpatient therapy services they furnish. Since 2014, most hospitals in Maryland are paid at rates determined under the Maryland All-Payer Model, which is being tested under the authority of section 1115A of the Act.

To correct this oversight, we recently issued instructions through Change Request 9223 (available online at <https://www.cms.gov/Regulations-and->

[Guidance/Guidance/Transmittals/Downloads/R3367CP.pdf](#)) to our Maryland MAC to revise our systems to ensure the application of the therapy caps and related provisions to the outpatient therapy services provided in all Maryland hospitals. These instructions included the direction to use the rates established under the Maryland All-Payer Model rather than the PFS rates to accrue towards the per-beneficiary therapy caps and thresholds. We believe using the Maryland All-Payer Model rates rather than the PFS rates is consistent with the statute at sections 1833(g)(1) and (3) of the Act that requires us to count the actual expenses incurred in any calendar year towards the beneficiary's therapy caps. These instructions will become effective January 1, 2016.

III. Other Provisions of the Final Rule With Comment Period

A. 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 proposed 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) and the CY 2015 PFS final rule with comment period (79 FR 67743)).

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. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the implementation of the extension of the ambulance payment add-ons. These commenters also agreed that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

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 in this section (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 proposed 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) and the CY 2015 PFS final rule with comment period (79 FR 67743 through 67744)).

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. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the continued implementation of the percent increase in the base rate of the fee schedule for transports in areas defined as super rural. These commenters also agreed with CMS that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

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 from stakeholders expressing concerns about the implementation of the new geographic area delineations finalized in that rule (as corrected). In response to these concerns, in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we clarified our implementation of the revised OMB delineations and the updated RUCA codes in CY 2015, and repropose the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent calendar years. We requested public comment on our proposals, which comments are further discussed in section III A.3.b. of this final rule with comment period.

b. Provisions of the Final Rule with Comment Period

Under section 1834(1)(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 in the June 28, 2010 **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 in the CY 2016 PFS proposed rule (80 FR 41788), 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/LTCH PPS 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, we believe that it was 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, in the CY 2016 PFS proposed rule (80 FR 41788), we proposed 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 stated in the CY 2016 PFS proposed rule (80 FR 41788) that 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 invited 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), the CY 2015 PFS final rule with comment period (79 FR 67745 through 67746) and the CY 2016 PFS proposed rule (80 FR 41788 through 41789). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13-01, which established revised delineations for MSAs, 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 website 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> and at <http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html>. We stated in the CY 2016 PFS proposed rule (80 FR 41789) that we believe the most recent RUCA codes provide more accurate and up-to-date information regarding the rurality of census tracts throughout the country. Accordingly, we proposed 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. We stated that 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) and in the CY 2016 PFS proposed rule (80 FR 41789), 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 proposed 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), the CY 2015 PFS final rule with comment period (79 FR 67745), and the CY 2016 PFS proposed rule (80 FR 41789), 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 website 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 proposed for CY 2016 and subsequent CYs, to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We stated that 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 did not propose in the CY 2016 PFS proposed rule (80 FR 41789) to 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 stated in the CY 2016 PFS proposed rule (80 FR 41789) that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We stated that 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 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 stated that we believe payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, 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 if we were to pay based on ZIP codes for

some areas and counties or census tracts for other areas. Therefore, we stated in the proposed rule (80 FR 41789) that, 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 invited public comments on our proposals, as discussed in in the CY 2016 PFS proposed rule, to continue to use the revised OMB delineations and updated RUCA codes under the ambulance fee schedule for CY 2016 and subsequent CYs.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41789 through 41790), 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 final rule with comment period, we are revising §414.610(c)(5)(ii) to conform the regulations to this statutory requirement. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), 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 final rule with comment period, we are revising §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Similar to our discussion in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), 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 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 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 in this section, we proposed 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. To determine which ZIP codes are included in each such rural census tract, we proposed 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 stated that we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB websites, 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 August 2015 USPS ZIP code file that we are using in this final rule with

comment period to assess the impacts of the revised geographic delineations, there are a total of 42,927 ZIP codes in the U.S. Table 23 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 August 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), and the CY 2016 PFS proposed rule (80 FR 41790 through 41791), as reflected in Table 23, 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 of all zip codes in the state. 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 of all zip codes in the state). As discussed in this section, these findings are illustrated in Table 23.

TABLE 23: 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%

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
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	42927	1600	3.73%	451	1.05%	40876	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 these changes, in addition to Table 23, the following files are available through the Internet on the Ambulance Fee Schedule website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html>, Downloads, CY 2016 Final Rule; 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.

We stated in the CY 2015 PFS final rule with comment period (79 FR 67750) and in the CY 2016 PFS proposed rule (80 FR 41792) that 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 stated in the CY 2016 PFS proposed rule (80 FR 41792) that we continue to believe 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 stated that 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 stated in the proposed rule that 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 did not propose a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs.

We invited 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 invited public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.

We received several comments from ambulance providers and suppliers and associations representing ambulance providers and suppliers on our proposals to continue implementation of the revised OMB delineations and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs. The following is a summary of those comments along with our responses.

Comment: A commenter supported our proposal to continue implementation of the new OMB delineations for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

Response: We appreciate the commenter's support of our proposal.

Comment: Several commenters agreed with CMS that it is appropriate to adjust the geographic area designations periodically so that the ambulance fee schedule reflects population shifts. These commenters remain concerned, however, because they contend that the modifications finalized last year have led to some rural ZIP codes being designated as urban. Several commenters urged CMS to refine the modified geographic area designations to restore rural status to those ZIP codes the commenters contended were improperly classified as urban last year. Specifically, commenters urged CMS to adopt HRSA's rural designations of 132

census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. According to the commenters, the discrepancy between CMS and HRSA in the application of RUCA codes appears to result from the fact that HRSA designates rural areas for its programs by focusing on the Census tract, while CMS focuses on a U.S. Department of Agriculture (USDA) ZIP code list. The commenters stated that it is important for these 132 Census tract areas to be taken into account for making geographic designations. The commenters suggested that CMS adopt a methodology to adjust the RUCA code status for the 132 census tracts recognized by HRSA as rural to RUCA code status 4 before cross walking the ZIP codes. According to the commenters, when the analysis is re-run, the resulting ZIP codes would be appropriately designated as rural. The commenters stated that by recognizing the 132 census tracts as rural, CMS's policy would align with HRSA's policy and address the concerns raised by ambulance providers and suppliers. According to the commenters, this approach would avoid the concerns that CMS has raised about splitting ZIP codes.

Response: We appreciate the commenters' support for adjusting the geographic area designations periodically to reflect population shifts. As discussed in this section and in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we believe that the most current OMB delineations, coupled with the updated RUCA codes, more accurately reflect the 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 enhances the accuracy of ambulance fee schedule payments. Further, as discussed previously, we believe that our methodology of designating rural geographic areas by using OMB's delineations, and by using RUCA codes of 4 and above to identify rural census tracts within MSAs, is appropriate for ambulance fee schedule payment purposes.

We have concerns with the methodology proposed by the commenters to identify as rural

certain census tracts with RUCA codes of 2 and 3. The 132 census tracts recognized as rural by HRSA have RUCA code designations of 2 or 3, indicating that the census tracts are predominantly urban. To assign these entire census tracts a RUCA code of 4 before cross walking the ZIP codes could result in inappropriate classifications of urban areas as rural. Payment under the ambulance fee schedule is based on ZIP codes (§414.610(e)). We would require a list of ZIP codes assigned to the 132 census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile to appropriately identify these areas as rural. As we previously discussed, we do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. We do not believe it would be prudent at this time to implement the commenters' suggested methodology absent the data and methodology to precisely identify the ZIP codes for the census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. We will consider further evaluating for CY 2017 these additional census tracts that HRSA has designated as rural and the feasibility of identifying the ZIP codes that are assigned to those areas.

Comment: Several commenters requested that CMS issue an Advanced Notice of Proposed Rulemaking (ANPRM) prior to the CY 2017 rulemaking cycle to seek input from all interested stakeholders about whether a new urban-rural data set should be used or other policy modifications should be adopted to apply the RUCA designations. According to the commenters, the data to determine the levels for RUCAs are no longer collected through the long-form census, which had a high response rate. The commenters contend that the RUCA data are now based on a response rate in the single digits which is not high enough to accurately identify urban-rural areas when it comes to access to vital ambulance services. The commenters stated that an ANPRM would allow CMS to hear from all interested parties at an early stage in the process and provide CMS with the information it needs to fully evaluate the current policy

and to identify options for addressing the issues that have been raised by commenters with RUCA being used as the data set for identifying rural census tracts within urban areas.

Response: The updated RUCA code definitions are based on data from the 2010 decennial census and the 2006-2010 American Community Survey (ACS). According to the United States Census Bureau's website, <http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html>, ACS is a nationwide survey that provides characteristics of the population and housing throughout the country, similar to the long-form questionnaire used in Census 2000. The ACS produces estimates of these characteristics for small areas and small population groups throughout the country.

According to the Census Bureau's website, the content collected by the ACS can be grouped into four main types of characteristics – social, economic, demographic, and housing. For example, economic characteristics include such topics as health insurance coverage, income, benefits, employment status, occupation, industry, commuting to work, and place of work. This is the same information that was collected by the 2010 Census.

The ACS is a continuous survey, in which, each month, a sample of housing unit addresses receives a questionnaire. For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. About 3.5 million addresses are surveyed each year. The ACS collects data from the 50 states, the District of Columbia, and Puerto Rico. The survey had the following response rates at the state level for 2006-2010: 91.1 percent to 99.0 percent in 2006, 91.7 percent to 99.3 percent in 2007, 91.4 percent to 99.4 percent in 2008, 94.9 percent to 99.4 percent in 2009, and 95.3 percent to 99.0 percent in 2010. The ACS collects survey information continuously and then aggregates the results over a specific period of time – 1 year, 3 years, or 5 years. The ACS period estimates describe the average characteristics of the population or housing over a specified period of time. For smaller geographic areas, such as the

census tracts, 5 year estimates are used. As mentioned in this section, the most recent update of the RUCA codes was developed using data collected from the 2006, 2007, 2008, 2009, and 2010 ACS. According to the Census Bureau, the estimates that they published based on the ACS had a 90 percent confidence interval.

According to the USDA's website, <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>, the RUCA codes were based on a special tabulation for the Department of Transportation, Census Transportation Planning Products, Part 3, Worker Home-to-Work Flow Tables (http://www.fhwa.dot.gov/planning/census_issues/ctpp/data_products/2006-2010_table_list/sheet04.cfm). According to the USDA, as with all survey data, ACS estimates are not exact because they are based on a sample. Nevertheless, we believe that the ACS provides the most recent comprehensive source of data on the population and is robust enough for use for purposes of determining the rural status of census tracts throughout the country.

We do not believe it is necessary to issue an ANPRM prior to the CY 2017 rulemaking cycle. In the CY 2016 PFS proposed rule and in past rules, we have discussed the implementation of the OMB delineations and the RUCA codes for purposes of payment under the ambulance fee schedule, and we believe that the public has had ample opportunity to provide comments and suggestions about other methodologies for designating geographic areas or other policy modifications that should be adopted to apply the RUCA code designations. We note that the public did not provide any suggestions for any alternative data sources for designating rural geographic areas.

We note that we utilize the ACS data in other Medicare payment systems as well. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), we finalized our proposal that the out-migration adjustments be based on commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, an official Census Bureau survey, utilizing 2008

through 2012 (5-Year) Microdata. (See also the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471)). Furthermore, the physician fee schedule uses the 2008-2010 ACS data for calculating the office rent component of the PE of the geographic practice cost index (78 FR 74390).

After consideration of the public comments received and for the reasons discussed in this section and in the CY 2016 PFS proposed rule, we are finalizing without modification our proposal 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 in this section, for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee schedule. As we proposed, using the updated RUCA code definitions, we will continue to designate any census tracts falling at or above RUCA code 4.0 as rural areas. In addition, as discussed in this section, none of the current super rural areas will lose their super rural status upon implementation of the revised OMB delineations and the updated RUCA codes.

4. Proposed Changes to the Ambulance Staffing Requirements

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, and, additionally, that 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.

As we stated in the CY 2016 PFS proposed rule (80 FR 41792), 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. In the CY 2016 PFS proposed rule, we stated that 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, in the CY 2016 PFS proposed rule (80 FR 41792), we proposed 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 proposed 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) (80 FR 41793). We stated that these 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 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, we stated in the proposed rule that we believe these proposals would enhance the quality and safety of ambulance services provided to Medicare beneficiaries.

In addition, we proposed 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 (80 FR 41793). 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 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 proposed 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 (80 FR 41793). This sentence 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 proposed 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 invited public comments on our proposals to revise the ambulance vehicle staffing requirements in §410.41(b) and the definition of Basic Life Support (BLS) in §414.605, as discussed in this section. We also stated that, if we finalized these proposals, we would revise

our manual provisions addressing ambulance vehicle staffing as appropriate, consistent with our finalized policy.

We received approximately 21 comments from ambulance providers and suppliers and associations representing such entities. The following is a summary of the comments we received along with our responses.

Comment: Several commenters supported the proposed changes to the ambulance staffing requirements. Commenters also requested that CMS support efforts to designate ambulance services as providers under the Medicare program (rather than having some designated as suppliers).

Response: We appreciate the commenters' support of our proposals. Comments requesting us to support efforts to designate ambulance services as providers are outside the scope of this final rule with comment period.

Comment: One commenter requested additional clarification on whether the proposed revision would require both ambulance medical technicians to be certified by the state as EMTs. This same commenter requested clarification on whether both technicians would need to be legally authorized to operate lifesaving and life-sustaining equipment on board the vehicle.

Two commenters opposed the proposed changes to the ambulance staffing requirements, expressing concern that the proposed changes would require both crew members to be certified as EMTs, a change they believed would negatively impact ambulance services in rural communities. One of these commenters stated that such a change would (1) not increase the level of care provided to the patient being transported, and (2) make it more difficult for volunteer Emergency Medical Services (EMS) providers to be properly reimbursed for their work. The commenters also stated that this requirement would limit access in rural communities, and that it would be difficult for volunteer EMS staff to meet such requirements.

Response: We believe that these commenters misinterpreted our proposal. We did not

propose to require that both ambulance crew members be certified as EMTs or that both ambulance crew members be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. The only change we proposed to our current policy was to require both ambulance vehicle staff to meet the requirements of state and local laws where the services are being furnished. Thus, our proposed policy would require that both ambulance vehicle staff be certified as EMTs only when this is required by the state or local laws where the services are being furnished. As we stated in the CY 2016 PFS proposed rule (80 FR 41942), because we expect that ambulance providers and suppliers already comply with their state and local laws, we expect that this requirement would have a minimal impact on ambulance providers and suppliers.

Comment: Several commenters supported the proposed revision to the definition of Basic Life Support (BLS) in §414.605 to delete the last sentence, which sets forth examples of certain state law provisions.

Response: We appreciate the commenters' support for our proposed revision to the definition of Basic Life Support (BLS) in §414.605.

After consideration of the public comments received, and for the reasons discussed in this section, we are finalizing without modification our proposals to revise (1) §410.41(b) and the definition of Basic Life Support (BLS) in §414.605, as discussed in this section, to require that all Medicare-covered ambulance transports be staffed by at least two people who meet both the requirements of state and local laws where the services are being furnished, and the current Medicare requirements, (2) §410.41(b) and the definition of Basic Life Support (BLS) in §414.605 to clarify that for BLS vehicles, one of the staff members must be certified at a minimum as an EMT-Basic, and (3) the definition of Basic Life Support (BLS) in §414.605 to delete the last sentence, which sets forth examples of certain state law provisions. We will also revise our manual provisions addressing ambulance vehicle staffing, as appropriate, to be

consistent with these finalized policies.

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) model 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 FR 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. Although 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 generally not included in the RHC or FQHC payment. We proposed 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 final rule, “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. Payment Methodology and Billing for CCM Services in RHCs and FQHCs

a. Payment Methodology and Billing Requirements

The requirements we proposed 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 24. We proposed to establish payment, beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that would be expected to last at least 12 months or until the death of

the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The CPT code descriptor sets forth the eligibility guidelines for CCM services and would 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 sub-regulatory guidance.

We proposed that a RHC or FQHC could bill for CCM services furnished by, or incident to, the services of a RHC or FQHC physician, NP, PA, or certified nurse midwife (CNM) for a RHC or FQHC patient once per month, and that only one CCM payment per beneficiary per month could be paid. If another practice furnishes CCM services to a beneficiary, the RHC or FQHC could not bill for CCM services for the same beneficiary for the same service period. We also proposed that TCM and any other program that provided 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. We proposed CCM payment for RHCs and FQHCs because we believe that the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

We proposed 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 was \$42.91 per beneficiary per calendar month.) This rate would not be subject to a geographic adjustment. 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 proposed 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 to RHC claims as applicable. 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.

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 did not propose 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 did not propose 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 did not propose 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 through the cost report. We did not propose 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. Requirements for CCM Payment in RHCs and FQHCs

a. Beneficiary Eligibility for CCM Services

Consistent with beneficiary eligibility requirements under the PFS, we proposed that RHCs and FQHCs receive payment for furnishing CCM services to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, as

determined by the RHC or FQHC practitioner, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We encouraged RHCs and FQHCs to focus on patients with high acuity and high risk when furnishing CCM services to eligible patients, including those who would be returning to a community setting following discharge from a hospital or SNF.

b. 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 were being furnished under the RHC AIR or FQHC PPS payment system.

Consistent with beneficiary notification and consent requirements under the PFS, we proposed 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 calendar month, 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. Scope of CCM Services in RHCs and FQHCs

We proposed 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), AWW, 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.
- The electronic care plan 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 to review the care plan criterion for health information technology (IT) finalized in the 2015 Edition of Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule (80 FR 62648), which aims to enable users of certified health IT to create and receive care plan information in accordance with the C-CDA Release 2.1 standard.

- 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. Such 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. 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 proposed 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 24: Summary of 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 visit.	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 appointments.	None.

CCM Scope of Service/Billing Requirements	Health IT Requirements
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 medications.	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 invited 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. The following is a summary of the comments we received and our responses.

Most of the comments we received were very supportive of our proposal to establish

payment for CCM services in RHCs and FQHCs. Several commenters agreed that allowing separate payment for CCM services in RHCs and FQHCs will better reflect the additional resources necessary for the unique services that are required to furnish CCM services to the populations served by RHCs and FQHCs. Many commenters appreciated that the proposed methodology would enable RHCs and FQHCs to be paid for these services even if there was no billable visit. A few commenters had concerns regarding health information technology requirements or beneficiary copayment requirements. One commenter had concerns about potential duplication in payment and increased Medicare spending. Several commenters requested clarification on specific aspects of the program. A few commenters asked questions that were beyond the scope of the proposal.

Comment: One commenter noted that in a few instances, our proposal alternately used “a CCM 30-day period” and “only one CCM payment can be paid per beneficiary per month.” The commenter stated that under the Medicare PFS and the definition of CPT code 99490, CCM services are based on a calendar month, not a 30-day period.

Response: The commenter is correct that the CCM period is based on a calendar month, not a 30-day period.

Comment: A few commenters were concerned that charging a beneficiary coinsurance for non-face-to-face services will be confusing to the beneficiary and create a barrier to receiving care. One commenter recommended that we waive coinsurance for CCM services, and another recommended that we waive the applicable coinsurance and deductible through CMMI’s waiver authority.

Response: We do not have the statutory authority to waive coinsurance for CCM services, and CMMI waiver authority is only applicable to CMMI demonstration programs. Although there may be potential for confusion on the part of the beneficiary who receives a bill for services that were conducted on their behalf but not furnished directly to them, this should be

fully explained to the beneficiary during the consent process and in subsequent patient interactions as necessary. We suggest that when practitioners explain the benefits of receiving CCM, they include the possibility that it may help the beneficiary to avoid the need for more costly face-to-face visits that would entail greater cost sharing.

Comment: A commenter was concerned that many beneficiaries and their caregivers will not fully understand the beneficiary consent for CCM services requirements, including what they are being asked to accept or decline, or why they are being asked to approve in writing the provision of certain services and not others. The commenter recommended that CMS take steps to ensure that beneficiaries will have a proper understanding of CCM and its value, as well as their right to decline enrollment in CCM, and that family caregivers be included in these conversations, whenever possible.

Response: We agree with the commenter regarding the importance of the beneficiary's understanding of CCM services and their right to accept or decline this service. Beneficiary education on CCM services, including information on the value of this service and the beneficiary's right to accept or decline it, is a required component of CCM services and must be provided to beneficiaries as part of the consent process. We also agree that these discussions should include the caregiver, when applicable.

Comment: A commenter urged CMS to ensure that communication methods are conducted in a culturally and linguistically appropriate manner. The commenter suggested that notices and agreements regarding CCM services should be written in plain language and in their patients' preferred languages, and be accessible to those with visual, hearing, cognitive, and communication impairments.

Response: RHCs and FQHCs serve diverse populations, and we thank the commenter for this important reminder that written and oral communication materials should be accessible and understandable to the patient population being served.

Comment: Some commenters expressed concerns with the proposed technological requirements for CCM services. They noted that interoperability and electronic exchange of medical information is costly and there are technological barriers that may prevent the seamless transmission and recording of patient information. One commenter stated that since RHCs and FQHCs were not eligible for Meaningful Use incentives, they may not have the health information technology in place to support some of the requirements, and that those RHCs and FQHCs that cannot meet the health information technology requirements will be excluded from payment for CCM services. Other commenters were concerned that some patients served by RHCs and FQHCs may not have the resources to receive secure messages via the Internet. These commenters recommended that the electronic health record requirements, and the electronic exchange of information and interoperability with other providers, be encouraged but not required for CCM payment.

Response: We appreciate the concern regarding the cost and challenges inherent in adopting new technological requirements and understand that not all RHCs or FQHCs may be able to meet the technological requirements at this time. RHCs and FQHCs that do not have an EHR system in place, or are not able to meet the CCM interoperability requirements, will not be able to furnish and bill for CCM services. However, based on recent surveys, we believe that many, if not most, RHCs and FQHCs have the capability to meet the technological requirements now or in the near future. For example, a recent survey showed that nearly 72 percent of RHCs have an operational EHR system, with 63 percent indicating use by 90 percent or more of their staff. The same study showed that slightly over 17 percent of RHCs without an EHR plan to implement one within 6 months, and 27 percent plan to do so within 7 to 12 months¹. A 2014 study showed that 93 percent of FQHCs have an EHR system, and that 76 percent reported

¹ Adoption and Use of Electronic Health Records by Rural Health Clinics: Results of a National Survey; Maine Rural Health Research Center, Research and Policy Brief, September 2015

meeting the criteria to qualify for meaningful use incentive payments². We would also note that eligible professionals working in RHCs and FQHCs are eligible to receive payment under the EHR Incentive Programs.

We are aware that not all patients, particularly those served by RHCs and FQHCs, may be able to receive secure messages via the Internet, and they are not required to do so. However, to furnish and bill for CCM services, RHCs and FQHCs must have the capability to communicate with the beneficiary and any caregiver, not only through telephone access, but also through the use of secure messaging, Internet, or other asynchronous non face-to-face consultation methods. Beneficiaries are not required to have this capability to receive CCM services.

Comment: One commenter disagreed with the proposed requirement that an electronic care plan be made available 24 hours a day, 7 days a week, and believes that this unrealistically fails to account for “system maintenance, down-time, change in EHR vendor, or the event of technological glitches and cyber-attacks”. The commenter recommended that at a minimum, CMS should provide for exceptions in the event of any of these circumstances.

Response: RHCs and FQHCs that choose to furnish and bill CCM services must have a system that supports 24 hours a day, 7 days a week, access to the electronic care plan. We understand that there may be times when the system is not operable, but we expect that this will not be a frequent occurrence.

Comment: A commenter stated that they were worried that adding very prescriptive technological requirements may stifle innovation and prevent the use of technology that is more appropriate and tailored for chronically ill patients. The commenter recommended that any technological requirements for CCM services should be broadly drafted to allow for future

² The Adoption and Use of Health Information Technology by Community Health Centers, 2009–2013;The Commonwealth Fund; Issue Brief; May 2014

changes and advancements over time.

Response: We appreciate the commenter's concerns about the need to avoid stifling innovation. In including these technology requirements, we are seeking to ensure that all RHCs and FQHCs furnishing CCM services have the technological capabilities that are needed to deliver high-quality services while allowing the flexibility needed to adopt appropriate technology solutions. By proposing the adoption of a minimal set of certified health IT capabilities, and allowing flexibility around more advanced capabilities such as shared care planning, we believe that these goals will be met.

Comment: A commenter stated that physicians have significant problems and usability concerns with the clinical care summaries, and recommended that these summaries not be required for CCM services.

Response: We respectfully disagree with this commenter's recommendation that clinical care summaries not be required for CCM services. We believe that the transmission of clinical care summaries is an important component of supporting effective care transitions and should be available electronically to effectively furnish CCM services.

Comment: A commenter stated that the proposed care plan for CCM services in RHCs and FQHCs, which includes the patient's medical, functional, and psychosocial needs and has system-based approaches for receipt of services, provides a comprehensive definition of care management that should be used in other CPT codes to assure consistency across programs and settings.

Response: We appreciate the comment, but the description of "care management" utilized in other CPT codes is outside the scope of this rule.

Comment: A commenter requested that CMS provide an optional patient-centered plan of care document template that can be used as an example to create a comprehensive care plan that is compliant with CCM requirements. Another commenter asked for clarification on the

documentation requirements for billing CCM services, and another stated that physicians are likely to need assistance from CMS in providing educational materials for their patients regarding CCM. A commenter urged CMS to expand the use of CCM codes to all Medicare beneficiaries.

Response: While we have not provided a template for RHCs and FQHCs to use in developing care plans, we would refer these commenters to the CMS website at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-02-18-Chronic-Care-Management-new.html> for general information on CCM, including educational materials.

Comment: A commenter requested that auxiliary personnel, including pharmacists, be allowed to provide CCM services in RHCs and FQHCs, including furnishing the AWW. Another commenter asked for clarification of what positions qualify as auxiliary staff.

Response: The CMS Benefit Policy Manual, Chapter 9, describes auxiliary personnel in RHCs and FQHCs as a nurse, medical assistant, or anyone acting under the supervision of the physician. Auxiliary personnel are not RHC or FQHC practitioners and cannot bill for a visit in a RHC or FQHC. However, the time spent by auxiliary personnel in furnishing CCM services could be counted towards meeting the 20 minute minimum requirement for billing a CCM visit.

Comment: A commenter urged CMS to recognize occupational therapy practitioners as RHC and FQHC practitioners, and to include occupational therapy in all CMS's efforts to ensure beneficiary care is appropriately provided and managed. The commenter states that this would assist in promoting patient self-management, reduce caregiver burden, decrease hospitalizations, increase effective resource utilization, and contribute to improved beneficiary and population health.

Response: We agree that occupational therapists can be a valuable and important part of the health care team and can contribute to improved outcomes and reduced costs. The full list of

statutorily-defined RHC and FQHC practitioners is set out at section 1861(aa)(2) of the Act, and includes physicians, NPs, PAs, CNMs, CPs, or CSWs. Other qualified practitioners, such as occupational therapists, may furnish services incident to a RHC or FQHC practitioner's services. For additional information on the provision of occupational therapy in RHCs and FQHCs, see the CMS Benefit Policy Manual, Chapter 13, on the CMS website at <https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html>, or <https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html>.

Comment: A commenter questioned what specific tasks can be counted toward the 20 minute CCM requirement.

Response: The tasks comprising CCM services are described in the scope of service requirements in section III.B. of this final rule with comment period.

Comment: A commenter urged CMS to emphasize and reiterate the scope of services that are expected, including 24-7 access to care management, continuity with a designated provider, and creation of a patient-centered care plan document.

Response: The scope of services that are required for CCM payment, including 24-7 access to care management, continuity of care with a designated provider, and creation of a patient-centered care plan document, are all required components of CCM services.

Comment: A commenter asked what would be considered the date of service for CCM if multiple days per month are used to get to the 20-minute mark.

Response: The service period for billing CCM services is one calendar month, and we expect the RHC or FQHC to continue furnishing services during a given month as applicable even after the 20-minute time threshold to bill the service is met. The RHC or FQHC could bill for the CCM service after completion of at least 20 minutes of qualifying CCM services during the service period, or any time after that until the end of the month. Additional billing

information will be provided in subregulatory guidance.

Comment: A commenter was concerned that CMS's proposed reimbursement level for CCM services in RHCs and FQHCs is low, and asked that we re-evaluate the time and effort needed for the appropriate provision of these important services.

Response: We proposed 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. Since the commenter did not provide any rationale or additional data supporting an increase in the payment rate for RHCs or FQHCs, we cannot address this comment.

Comment: A commenter was concerned that separate payment for CCM services in RHCs and FQHCs may lead to duplicative payments because the FQHC PPS payment reflects the costs for all services associated with a comprehensive primary care visit, even if not all the services occur on the same day. The commenter also suggested that separate payment for CCM services could lead to duplicative payment for FQHCs that receive a Public Health Service grant because the grant already requires the provision of health services that are available and accessible promptly and in a manner which will assure continuity of service to the residents of the center's catchment area.

Response: We would like to alleviate any concerns that separate payment for CCM services is a duplication of RHC and FQHC payment. Although the FQHC PPS payment, and the RHC AIR, do reflect the costs for all services associated with a comprehensive primary care visit, even if not all the services occur on the same day, it does not generally include the costs of the services required for CCM payment. For example, FQHCs are required to provide case management that includes an assessment of factors affecting health (for example, medical, social, housing, or educational), counseling and referrals to address identified needs and periodic follow-up of services. They are not required to create a structured recording of demographics,

problems, medications, medication allergies, and structured clinical summary records using CCM certified technology, or to share the care plan as appropriate with other practitioners and providers. FQHCs are required to have an on-call provider for after-hours care, but they are not required to have the 24/7 case management services that the CCM billing code requires. RHCs do not have these requirements for primary care visits.

In general, although a few of the services required for CCM payment may be provided by some RHCs and FQHCs on occasion, the systematic provision of care management, the level and intensity of care coordination, and the interoperability of care plans with external providers is not typically found in RHCs or FQHCs.

Comment: A commenter noted that the increase Medicare expenditures for CCM services in RHCs and FQHCs would not trigger a budget-neutrality adjustment, even though the estimated increase in spending is material.

Response: The commenter is correct that payment for RHC and FQHC services is not subject to budget neutrality. We believe that the additional cost for furnishing CCM services in RHCs and FQHCs is an investment in comprehensive and coordinated care that is likely to be offset by reduced hospitalizations and readmissions. We would also note that, based on the current utilization under the PFS, we have revised our original estimate to reflect the expected phased in rate of CCM utilization.

Comment: A commenter stated that FQHCs should not be required to exclude any activities related to CCM from their Medicare cost reports.

Response: Any cost incurred as a result of the provision of CCM services (as defined in the task list in section III.B.) is an allowable cost and should be included in the Medicare cost report.

Comment: A commenter requested that CMS clarify in the final rule that Medicare Advantage (MA) enrollees are entitled to the same CCM services as non-MA enrollees, and that

MA-contracted FQHCs are entitled to the same payment for CCM services as FQHCs providing qualifying CCM services to non-MA enrollees.

Response: In addition to Medicare Part A and Part B services, MA organizations (MAOs) are required to furnish care coordination services that are substantially similar to the Original Medicare CCM services. They have flexibility in terms of how to furnish care coordination services to ensure ongoing continuity of care and care management for all enrollees. MA regulations at §422.256(a)(2)(ii) expressly preclude CMS from interfering in payment rates agreed to by an MA plan and its contracted providers. Whether or not a MAO pays its providers for furnishing care coordination services through use of the CPT code or some other mechanism can vary depending on the contract agreement in place. Thus, the amount the MA plan will pay the contracted FQHC depends on the terms of the contract. We note that MA PPO enrollees have the option to obtain covered services from non-contracted providers. Thus, if a PPO enrollee chooses an out-of-network provider to furnish chronic care management services and all criteria for billing the CCM code is met, the MAO must pay for those services consistent with Original Medicare payment rules. In this scenario, enrollees are responsible for any plan established out-of-network cost sharing. Additionally, although not coordinated care plans, Medicare PACE Organizations, MA private fee-for-service plans and MA Medicare Savings Account plans are required to cover Medicare Part A and Part B services, which include coverage of the CCM services consistent with Medicare coverage and payment rules.

Comment: A commenter stated that RHCs and FQHCs cannot bill for an IPPE or AWW visit in addition to the AIR and that RHCs and FQHCs are doing this work at their own expense and without compensation. The commenters stated that CMS has proposed the ability for RHCs to bill for CCM in addition to the AIR in the CY 2016 PFS, and asked that this RHCs and FQHCs also be allowed to bill separately for the IPPE and AWW.

Response: It is unclear why the commenter stated that the IPPE and AWW are

uncompensated, since these services are billable visits. Although we do not agree that RHCs and FQHCs are furnishing IPPEs and AWWs at their own expense and without compensation, payment for IPPEs and AWWs in RHCs and FQHCs is outside of the scope of this proposal.

Comment: A commenter expressed concern that the unique RHC and FQHC billing structures may preclude them from receiving payment for newly developed care coordination payment codes, and suggested that RHCs and FQHCs be guaranteed care coordination payments. The commenter stated that including RHCs and FQHCs in ensuring better care coordination is vital, and suggested that CMS make payments for care coordination services available to RHCs and FQHCs through “crosswalk” procedures or similar technical allowances,

Response: We agree that care coordination in RHCs and FQHCs is extremely important, and would note that the payment methodology proposed for RHCs and FQHCs is due to the non-face-to-face nature of this benefit. As the commenter did not provide any specific suggestions on “crosswalk procedures or similar technical allowances,” we cannot address this comment.

Comment: A commenter requested that PAs in RHCs be allowed to bill for laboratory, X-rays, and other services using a methodology similar to what was proposed for CCM services.

Response: This comment is outside the scope of this rule.

Comment: A few commenters requested that an exception to the direct supervision requirements be made for CCM and TCM services that are furnished incident to physician services in RHCs and FQHCs. The commenters suggested that the regulatory language be amended to be consistent with the provisions in §410.26(b)(5), which state that CCM and TCM services (other than the required face-to-face visit) can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

Response: We believe that due to their different model of care and payment structure, requiring direct supervision for “incident to” services is appropriate for RHCs and FQHCs at this time. However, we will consider this for future rulemaking if RHCs and FQHCs find that requiring direct supervision presents a barrier to furnishing CCM services.

Comment: A commenter stated that the limitation of one CCM payment per month per beneficiary does not support the scope of services that beneficiaries often need.

Response: We are not sure if this commenter is suggesting that CCM payments be made more frequently to the same RHC or FQHC (or other practitioner), or if more than one entity (for example, RHC, FQHC, a physician’s office, etc.) should be able to bill for CCM services within the month. For either of these situations, we respectfully disagree with this commenter. We believe that a minimum of 20 minutes of CCM services over a one-month period is required to achieve the benefits of CCM services, and that there should be a single and consistent point of contact for these services.

Comment: A commenter recommended the creation of a modifier for services furnished by a specialist to establish a link between a primary care referral and the specialist for CCM.

Response: Since services furnished directly by a primary care practitioner or a specialist are separately billable services, we believe this commenter may be suggesting a way to document referrals to specialist services that result from CCM services. We thank the commenter for the suggestion but do not believe this would be necessary or beneficial.

As a result of the comments, we are finalizing these provisions as proposed, except to change “30-day period” to “calendar month” wherever it was used in the proposed rule.

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 report 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, RHCs have been required to report HCPCS coding for these preventive services, for which coinsurance and deductible are waived. 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. 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(1)(a) 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 proposed 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 proposed that RHCs exempt from electronic reporting under section 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 proposed 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 also proposed 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 proposed 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 invited 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.

The following is a summary of the comments we received and our responses.

Comment: We received a few comments on our proposal and all were supportive of

requiring RHCs to report HCPCS for all services furnished. Most commenters agreed with our assertions that the data could potentially inform future policy decisions by providing useful information on individual patient attributes and the types of services/procedures furnished by RHCs. One commenter supported this proposal because currently all other providers such as hospitals, physicians, and FQHCs report HCPCS on claims to Medicare. Another commenter expressed interest in reporting HCPCS to enable participation in PQRS and other quality reporting programs. A commenter stated that HCPCS could be determined from the services recorded in the electronic medical record system and office systems that generate claim forms could be modified easily to bill all services furnished. A commenter believed that the majority of RHCs would experience minimal burden fulfilling this requirement. Although all commenters supported the requirement, a few commenters raised concerns about operational challenges of the requirement. One commenter stated, “The operational challenge for providers will be capturing the appropriate charge for ‘all’ services provided.” Another commenter was concerned about whether CMS and the MACs would be ready by January 1, 2016 to process RHC claims under the proposed requirement.

Response: We appreciate the support for our proposal to require RHCs to report HCPCS on RHC claims for Medicare services. We want to clarify that the reporting of HCPCS does not necessarily convey eligibility to participate in PQRS and other value-based payments since these programs have additional eligibility requirements that RHCs may be unable to meet. We do not believe there will be an operational challenge for providers to capture the charge for all services provided. There is no change to the methodology for reporting charges under this requirement. We acknowledge the commenter’s concerns about the system’s readiness to process claims under the requirement and we have been working with the MACs to implement the required updates. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016 to allow the MACs additional time to implement the necessary claims processing systems

changes completely.

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, Pub. 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, Pub. 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)), Pub. L. 83-568 (42 U.S.C. 2001(a)), and the IHCIA, 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 CY 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. Commenters 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.

However, the Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at §482.12 require administrative and clinical integration between a hospital and its provider-based clinics, departments, and locations. 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, it became apparent that a different structure was 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. We believed that the FQHC

program may provide an alternative structure that met the needs of these tribal clinics and the populations they served, while also ensuring the IHS hospitals were not at risk of being cited for non-compliance with the requirements in their CoPs.

c. Federally Qualified Health Centers (FQHCs)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508, enacted on November 5, 1990) (OBRA 90), 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 IHCA.

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” for FQHCs. 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), as added by the Affordable Care Act, requires that Medicare payment for FQHC services under section 1834(o) of the Act 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 statute, as amended by 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 CY 2016 by the 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 under 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. Payment Methodology and Requirements

We proposed that IHS and tribal facilities and organizations that met the conditions of §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 referred 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 proposed 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 proposed that these grandfathered tribal FQHCs would be paid based on the IHS payment rates and not the FQHC PPS payment rates, we also proposed 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 proposed not to apply the MEI or a FQHC market basket adjustment that is applied annually to the FQHC PPS base rate. We proposed 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. 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 final rule with comment period. Therefore, we proposed 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 was 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 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 proposed 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.

We invited public comments on all aspects of our proposal to allow IHS and tribal facilities and organizations that met the conditions of §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, to become certified as grandfathered tribal FQHCs.

We received comments on this proposal from the Alaska Native Health Board, Alaska

Native Tribal Health Consortium, Citizen Potawatomi Nation, Southern Ute Indian Tribe, Southcentral Foundation, and the Tribal Technical Advisory Group (TTAG). All the commenters were strongly opposed to the proposal and requested that it be either withdrawn or revised.

The following is a summary of the comments we received and our responses.

Comment: Commenters questioned the necessity of changing the payment system for grandfathered tribal outpatient clinics that are no longer provider-based to a hospital, and cited our history of interpreting and applying the provider-based regulations in a manner which granted provider-based status to these clinics even though they do not meet the provider-based requirements.

Response: In the proposed rule, we stated several reasons for proposing that these grandfathered tribal outpatient clinics transition to grandfathered tribal FQHC status. First, a grandfathered tribal outpatient clinic billing under an IHS hospital's CCN, without any administrative or clinical relationship with the IHS hospital, violates our hospital CoPs, which as noted, requires a hospital to function as one integrated entity, no matter how many off campus locations it may have. This would include having one governing body, one organized medical staff, one organized nursing department, one quality assessment and improvement program, and so forth. Non-compliance with any CoP requirement is cited as non-compliance for the entire hospital (§482.12). Serious noncompliance in any part of the hospital puts the entire hospital at risk for termination of its Medicare agreement, which would impact not just the hospital, but also the community it serves.

Second, a hospital may be legally liable for actions that occur by any part of their organization, which would include a clinic that is billing for Medicare services under the hospital's CCN, even if the hospital exercises no control over the clinic. We believe this puts a

hospital in the untenable position of being legally responsible for actions over which it has no control.

Finally, under the current practice, grandfathered tribal outpatient clinics receive Medicare payment for services to Medicare beneficiaries and are subject to the hospital's CoPs. The Medicare CoPs are sets of requirements for acceptable quality in the operation of health care entities that must be met in order to bill Medicare, and an entity cannot participate in Medicare unless it meets every Condition. Because the facility would no longer be associated with a hospital, we believe that the FQHC CoPs would be an appropriate standard that all of these clinics would be able to meet.

For these reasons, we believe it is prudent for grandfathered tribal outpatient clinics to be directly responsible for their operations and held to Medicare CoPs that are reasonable and achievable, and that the option to become grandfathered tribal FQHCs will achieve these goals.

Comment: Commenters stated that provider-based status is already guaranteed under existing law and does not jeopardize the Medicare certification of IHS hospitals.

Response: As discussed in the previous response, a hospital that is not in compliance with its Medicare hospital CoPs is at risk for termination of its Medicare certification. The CoPs at §482.12 and §485.627, as applicable, require that each hospital have a governing body legally responsible for its operations, and do not provide an exception where a tribal clinic is billing as an outpatient department of the hospital but otherwise has no clinical or administrative relationship with that hospital. As we discussed in the proposed rule, a letter was issued to Trailblazer Health Enterprises, LLC, on August 11, 2003, 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. This letter has been interpreted by some as the basis for allowing tribal clinics that no longer meet the provider-based requirements to maintain their provider-based status and continue to be paid as an outpatient department of a hospital. We would note that although this letter acknowledged the continued provider-based status of some tribal clinics, no statute guarantees provider-based status to outpatient departments of hospitals that have changed their status such that they are no longer integrated with the hospital under whose Medicare CCN they are billing.

Comment: Commenters stated although they believe no clarification is needed, CMS could amend the regulations to state that (1) IHS and tribal facilities qualify for grandfathered provider-based status solely by virtue of satisfying §413.65(m) and that (2) changes in the IHS or tribal status of a hospital or facility's operation will not lead to the loss of provider-based status, or jeopardize the associated hospital's Medicare certification, if the resulting configuration would have qualified as a grandfathered provider-based tribal facility as of April 7, 2000. Alternately, CMS could reaffirm its longstanding reading of the regulations as stated in the preamble to the CY 2000 PFS final rule.

Response: We appreciate the suggestion, but neither of these approaches would relieve the hospital from liability for CoP violations found in a grandfathered tribal provider-based clinic using the hospital's CCN, or, in the alternative, address the lack of applicable CoPs for tribal clinics claiming to operate as outpatient departments of a hospital with which they do not otherwise have an administrative or clinical relationship.

Comment: Commenters requested that CMS withdraw the proposed rule, or make the grandfathered tribal FQHC status optional for eligible tribal facilities and allow them time to compare the alternatives and make an informed choice.

Response: We stated in the proposal that IHS and tribal facilities and organizations that met the conditions of §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. Although we would encourage all facilities that qualify for this status to become certified as grandfathered tribal FQHCs as soon as possible, they are not required to do so. We do, note, however, that CMS has an obligation to enforce compliance with the hospital CoPs at §482.12. Thus, if CMS were to survey a hospital, and find Medicare being billed for hospital outpatient services by a provider-based department that was not in compliance with the hospital CoPs, the hospital would have to submit an acceptable plan of correction consistent with provisions of §488.28 and demonstrate compliance via an on-site survey or risk termination of its Medicare certification. Such an action could potentially lead to an interruption in Medicare Part B payments for the tribal facility. It is for this reason that we would encourage all facilities that meet the requirements to be grandfathered tribal FQHCs to transition to this status at the soonest possible time.

Comment: Commenters stated that the proposed change would disrupt operations at the affected tribal facilities and potentially disqualify them from receiving any Medicare payments between the time they lose their grandfathered provider-based status and the time they qualify for the grandfathered tribal FQHC certification. Commenters stated that CMS has not indicated when a currently grandfathered tribal provider-based clinic will be deemed to lose that status, or how they should bill and be paid during the interim period between submitting the Form 855A and ultimately receiving their first payment as a grandfathered tribal FQHC.

Response: We recognize that any change, especially one as significant as a change in a payment system, can be disruptive. We have taken numerous steps to assure that there would be no gap in Medicare payments between the time that one of these clinics ceases billing as a grandfathered tribal outpatient clinic and begins billing as a grandfathered tribal FQHC. We

contacted the tribal clinics that would be eligible for grandfathered tribal FQHC certification and held several training calls to explain the proposed changes. We pledged to work closely with the tribes and affected clinics throughout the process to assure that the transition proceeds as smoothly as possible. We also note that other clinics have gone through similar transitions in payment systems, and we expect that this one would also be implemented with minimum disruption.

Comment: Commenters expressed concern regarding tribal preparedness to transition to a new payment system and the lack of technical assistance to date. The commenters noted that tribal facilities are unfamiliar with the FQHC rules and are apprehensive about what this change will entail in terms of reimbursement rates and covered services, as well as the legal and technical costs associated with the transition. Commenters stated that the lack of technical assistance will discourage tribes from transitioning to grandfathered tribal FQHC status. The commenters requested that CMS provide extensive and ongoing technical assistance to facilitate this transition, including practical training for tribal billing offices and financial officers and associated legal analysis for tribal attorneys and technical advisors. Commenters also requested a “reasonable transition period” and a “generous grace period” for any facility that must change to grandfathered tribal FQHC status, and suggested that these clinics be allowed twelve months before they are required to submit an application to become a grandfathered tribal FQHC.

Response: We understand the apprehension associated with changes that may impact the financial operations of a clinic. Following the issuance of the CY 2016 PFS proposed rule, we held several public calls to further explain the grandfathered tribal FQHC proposal. An “All Tribes Call” was held on July 29, 2015, to review the proposed rule, including eligibility, certification and billing requirements, and transitioning to the new system for grandfathered tribal FQHCs. This was followed by an August 12, 2015, call with the Northeast Tribal Health Consortium, and an August 26, 2015, call with the Osage Nation, and a call on September 30

with the Southern Ute and Alaska tribes. Members of and advisors to the TTAG also participated on all of these calls. A slide presentation was provided to outline key components of the proposed rule and we were available to answer any questions. During these calls, we reaffirmed our commitment to assisting these clinics in the transition and providing technical assistance as appropriate and necessary.

We also held calls with the CMS Regional Office Survey and Certification staff in the regions that have clinics eligible for this transition, and with the MAC responsible for the processing of claims and payment to these clinics, to ensure that they are aware of the proposal and are prepared to assist clinics as necessary in the transition. Subregulatory guidance on payment policies and claims processing will be available following publication of the final rule with comment period.

We intend to continue to provide technical assistance to affected clinics to facilitate the transition to grandfathered tribal FQHC, but we cannot provide training for financial officers or legal analysis.

Comment: Commenters were concerned that once a clinic self-attests or is informed by CMS that it no longer satisfies grandfathered provider-based tribal clinic status, it would not be able to bill Medicare at all until the clinic receives its Medicare CCN as new grandfathered tribal FQHC. Commenters also requested assurance that Medicare payments made to a grandfathered provider-based tribal clinic for services it provides between the date CMS determines it has lost provider-based status, and the date it begins billing as a grandfathered tribal FQHC, will not be treated as overpayments.

Response: We will assist eligible tribal outpatient departments with the transition to status as grandfathered tribal FQHCs so that there will be no overlap or gap in Medicare certification or payment. Further instructions on billing and claims processing will be provided in subregulatory guidance.

Comment: Commenters stated that the proposed change would dramatically lower their reimbursement rates.

Response: We respectfully disagree with this comment. We proposed to set the grandfathered tribal FQHC PPS rate at the same rate that the clinics are currently billing as grandfathered tribal outpatient clinics, subject to the FQHC PPS statutory requirement of paying 80 percent of the lesser of actual charges or the PPS rate. We note that this rate is significantly higher than the FQHC PPS rate and higher than payments made under the PFS. Although we have designed the proposal such that it continues to pay the same rate per encounter, we also note that services covered under the FQHC benefit differ from those covered under the hospital outpatient benefit, so an exact comparison is not possible. For example, the IHS hospital outpatient department's AIR includes technical services such as lab and X-rays. Under the FQHC PPS, these services are separately billable by the facility. The FQHC's per-diem payment includes practitioner services, and these services are separately billable under the IHS hospital outpatient department's AIR. The final payment under both systems is a result of the clinic's charges and the mix of services that are furnished by the particular clinic. Both IHS hospital outpatient departments and grandfathered tribal FQHCs are paid a single per diem visit for Medicare beneficiaries.

Comment: Commenters stated that grandfathered tribal FQHCs would see a reduction in their Medicare reimbursement because they would be paid "the lesser of" their charges or the grandfathered tribal FQHC PPS rate, and because the FQHC PPS rates include the professional services for which provider-based tribal facilities receive separate reimbursement in addition to their Medicare outpatient per-visit payment. Commenters stated that the grandfathered tribal FQHC will only be paid at the IHS hospital outpatient department's AIR if the G-code-based charges are higher than the AIR, and that this will result in a cap on their payment instead of a floor or a guarantee, as it is under the provider-based payment methodology. The commenters

also stated that the proposed payment methodology will result in lost revenue for facilities assumed by tribes under the ISDEAA and would hamper the financial feasibility of tribes assuming the responsibility to carry out IHS programs. The commenters believe that this would contradict congressional intent to encourage self-determination and self-governance by tribes through the exercise of their rights under the ISDEAA.

Response: Grandfathered tribal FQHCs, like all FQHCs, would be paid the lesser of their charges or the grandfathered tribal FQHC PPS rate. This is in accordance with section 1833(a)(1)(Z) of the Affordable Care Act, which requires 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.

As noted in the previous response, the services included in the FQHC benefit are different than the services included in the IHS hospital outpatient department AIR, and a direct comparison in Medicare payments cannot be made without factoring in the clinic's charges and the mix of services that are furnished. We have no reason to believe that there will be a significant increase or decrease in Medicare payments to those clinics that become grandfathered tribal FQHCs.

We fully support the rights of tribes to take over IHS facilities under the ISDEAA, and believe that the proposed payment system will enable tribes to continue to exercise self-determination and self-governance of their health care services. These clinics currently have the option of billing for Medicare services as a standard FQHC which has a 2015 PPS payment rate of \$158.85, or billing for Medicare services separately under the PFS. We believe the proposed grandfathered tribal FQHC PPS rate, with an adjusted 2015 PPS rate of \$307, will enable these clinics to provide Medicare services and bill at approximately the same rate.

Comment: Commenters stated that the proposed G code system is vague, and that little guidance has been provided as to how tribal health programs should go about determining the

charge levels for their G codes. The commenters cited a July 29, 2015 “All Tribes Call” where CMS explained that charges must be “reasonable” and “uniform for all patients, regardless of insurance status.” The commenters stated that what constitutes a “reasonable medical charge” is highly context-specific, and usually includes some combination of analyzing the relevant market for hospital services, the usual and customary rate the hospital charges, the hospital’s internal cost structure, the nature of the services provided, the average payment the provider would have accepted as full payment from third-parties, and the price an average patient would agree to pay for the service at issue. Commenters stated that it would be difficult for tribal facilities to know whether or not they are devising charge rates that would withstand judicial scrutiny if challenged as unreasonable, that tribes will have to devote additional time, resources, and legal analysis to devising G codes, and the G codes will likely vary from tribe to tribe for providing identical services to the same patient population. Commenters requested consultation to develop uniform standards as to what constitutes reasonable charges for the purposes of grandfathered tribal FQHC payments. The commenters also noted their preference to eliminate the charge-based “lesser of” G-code standard and instead authorize grandfathered tribal FQHCs to be paid as if they were provider-based outpatient hospital departments.

Response: Eliminating the charge-based “lesser of” G-code standard and instead authorizing grandfathered tribal FQHCs to bill as if they were provider-based hospital outpatient departments is not legally permissible. As previously noted, section 1833(a)(1)(Z) of the Affordable Care Act requires 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.

As discussed in the proposed rule, there are five FQHC G codes (G0466–FQHC visit, new patient; G0467–FQHC visit, established patient; G0468–FQHC visit, IPPE or AWW; G0469–FQHC visit, mental health, new patient, and G0470–FQHC visit, mental health,

established patient). Each grandfathered tribal FQHC would determine which services to include in each G code, based on the services typically furnished per diem by that grandfathered tribal FQHC to their Medicare patients. Once the typical bundle of services in each G code is established, the grandfathered tribal FQHC would total their normal charges for those services. The sum of the charges for the services included in the bundle of services is the G code amount. Since grandfathered tribal outpatient clinics already have established charges for their services, it should not be difficult for them to establish their G codes.

Consistent with longstanding policy, the use of these payment codes does not dictate to providers how to set their charges. A grandfathered tribal FQHC would set the charge for a specific payment code pursuant to its own determination of what would be appropriate for the services normally provided and the population served at that grandfathered tribal FQHC, based on the description of services associated with the G code. The charge for a specific payment code would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary.

In setting its charges, a grandfathered tribal FQHC would have to comply with established cost reporting rules in §413.53 which specify that charges must reflect the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Each grandfathered tribal FQHC would establish charges for Medicare visits that reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that the FQHC would furnish per diem to a Medicare beneficiary. We note that establishing Medicare per diem rates that are substantially in excess of the usual rates charged to other paying patients for a similar bundle of services could be subject to section 1128(b)(6) of the Act, as codified at 42 CFR 1001.701.

Comment: Commenters objected to withdrawing grandfathered provider-based status for

certain tribal facilities and replacing it with a new status that is untested and poorly understood and may not fit their administrative and clinical operations.

Response: FQHCs began transitioning from an AIR payment system to the FQHC PPS on October 1, 2014. The system was thoroughly tested prior to implementation, and FQHCs have been submitting claims and receiving payment under this system without disruption. The proposed grandfathered tribal FQHC payment is an adjustment under the FQHC PPS to maintain the same payment rate that these clinics previously billed Medicare. Therefore, we do not agree that the system is untested or poorly understood, although we understand that it would be new for those clinics that choose to transition to become grandfathered tribal FQHCs. We created this option because we believe that the FQHC model most closely aligns with the operations of tribal outpatient clinics, and being included in this benefit category would enable these tribal clinics to continue their services and meet the Medicare CoPs.

Comment: Commenters requested that CMS extend grandfathered provider-based status to certain tribal facilities in Oklahoma, and perhaps other locations, which were denied that status because of errors committed by federal agencies.

Response: This comment is beyond the scope of this rule.

Comment: Commenters stated that the proposed rule is unclear whether Alaska clinics that become grandfathered tribal FQHCs would be paid at the \$564 Alaska Medicare outpatient rate, or at the \$307 rate that applies in the lower 48 states, and stated that if the proposal is finalized, Alaska facilities should be paid at the higher Medicare outpatient hospital rate that reflects their higher cost of services.

Response: At this time, it is our understanding that there are no IHS or tribal facilities in Alaska that are eligible to become grandfathered tribal FQHCs. However, it is our intention that the reference to the payment rate in §405.2462(d)(4) would include the rates specific to facilities in Alaska pursuant to the IHS reimbursement rates. In the event that any Alaska facilities are

eligible and convert to a grandfathered tribal FQHC, the specific rates for facilities in Alaska would apply.

Comment: Some commenters were concerned that CMS might propose further reimbursement reductions for these clinics because the proposed rule states that CMS “will monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.”

Response: We have a responsibility to assure that Medicare Trust funds are utilized in accordance with Congressional intent and make adjustments to payments as necessary. Any changes to the payment methodology would be made through notice and rulemaking and with appropriate tribal consultation.

Comment: A commenter was concerned that the proposed regulation may impose more stringent physician supervision requirements than those that apply to provider-based clinics under the Medicare Part A and B rules and that it may be difficult or impossible for some affected clinics to meet these more stringent requirements, particularly those in remote locations where there are few or no physicians and services are provided primarily by mid-level practitioners or through the use of telemedicine. The commenter requested that grandfathered tribal FQHCs be exempt from physician supervision and other clinical requirements that are more stringent than those that apply to grandfathered provider-based programs.

Response: Grandfathered tribal outpatient clinics that choose to transition to become a grandfathered tribal FQHC will be required to be in compliance with the Medicare CoPs and other Medicare FQHC requirements and policies, unless such provisions are in conflict with applicable Federal law. Medicare requires most hospital outpatient services to be furnished under direct supervision as a condition of payment, including services furnished in a location that is a provider-based department of the hospital. FQHC practitioners practice under general supervision requirements and in accordance with state licensure requirements. However, state-

specific licensure requirements are exempted for IHS and tribal programs under section 25 USC 1647a of the IHCA. General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the furnishing of the service. We also note that the FQHC conditions for coverage generally impose significantly fewer regulatory burdens on facilities than the hospital CoPs that would otherwise apply.

Further instructions on Medicare CoPs for participation for grandfathered tribal outpatient clinics will be provided in subregulatory guidance.

Comment: A commenter requested confirmation that the governing board exception for tribes under section 330 of the PHS Act (42 U.S.C. 254b) would apply to grandfathered tribal FQHCs.

Response: We believe that the commenter is referring to section 330(k)(3)(H) of the PHS Act, and specifically to the exception to the requirements in section 330(k)(3)(H) (i)-(iii) of the PHS Act for entities operated by an Indian tribe or tribal or Indian organization under the ISDEAA or an urban Indian organization under the IHCA. A grandfathered tribal FQHC that is operated by one of the aforementioned entities would not be required to meet the governing board requirements in section 330(k)(3)(H) of the PHS Act. The governing board exemption would not apply to an IHS clinic operating as a FQHC look-alike that meets the requirements for a grandfathered tribal FQHC.

Comment: Commenters expressed disappointment with the extent and quality of tribal consultation that has occurred and believe that CMS should have consulted with the TTAG prior to issuing the proposed rule. The commenters referenced a letter sent to CMS on July 9, 2015, in response to a request for more information regarding the grandfathered provider-based status of tribal clinics and why their associated hospitals maintain Medicare certification absent administrative or clinical integration. Commenters stated that they expected CMS to study the

letter and give it due consideration before issuing a proposed rule, but CMS released the proposed rule without prior tribal consultation or consideration of the TTAG's analysis, despite their request for further discussion prior to any action.

Response: On February 18, 2015, CMS representatives met with the TTAG to discuss the concerns regarding outpatient tribal clinics billing Medicare as provider-based clinics to IHS hospitals. In response to comments made during the discussion, we requested that the TTAG send additional information that explains the TTAG's understanding of the provider-based rules and how they apply to these clinics.

We appreciate the detailed and thoughtful information that was provided by the TTAG in their July 9, 2015 letter. We regret that the letter was not provided in time to be addressed in the CY 2016 PFS proposed rule that was issued on July 8, 2015.

Comment: Commenters stated that CMS should have consulted with the TTAG and tribes nationwide prior to issuing the proposed rule. Commenters requested that CMS withdraw the proposal and engage in further tribal consultation before releasing a proposal. The commenters requested that CMS consult with the TTAG and other tribal stakeholders in the future before issuing proposed changes to regulations that affect tribes.

Response: We have a long history of tribal consultation on issues pertaining to tribes, and the discussions that have occurred have had a significant and beneficial influence on our policies. We believe that the tribal consultation that occurred prior to the publication of the proposed rule was both adequate and informative. We are subject to the provisions of the Administrative Procedure Act (APA) (5 U.S.C.), and external discussions on the development of proposed rules are limited during the regulatory process. We met with the TTAG before developing the proposed rule, and have had several national calls (as noted above) since the proposed rule became public. We look forward to continuing our dialogue with the TTAG and the tribes regarding this and any other Medicare issue that affects tribes.

Comment: Commenters requested the formation of a Tribal-CMS provider-based status workgroup prior to CMS issuing a final rule, as well as nationwide tribal consultation concerning CMS's interpretation of the proposed rule and applicable requirements. The commenters stated that consultation must go beyond providing comments on a proposed rule.

Response: Formation of a Tribal-CMS workgroup is not in the purview of this final rule. We suggest that the commenters make this request through the CMS Division of Tribal Affairs. As noted above, the process for regulatory notice and comment is in accordance with the APA.

Comment: Commenters requested that the proposed revisions at §405.2462(d)(1)(ii) that defines a grandfathered tribal FQHC be revised to ensure that grandfathered provider-based tribal facilities qualify for the new tribal FQHC status so long as they fulfilled the applicable grandfathering requirements as of the relevant date.

They also suggested that because eligibility for becoming a grandfathered tribal FQHC applies to clinics that had provider-based status on or before April 7, 2000, tribal clinics that were provider-based before but not on April 7, 2000, should be eligible for grandfathered tribal FQHC status.

Response: The proposed rule stated that grandfathered tribal FQHC status would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based on or before April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally operated hospital, and that 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. We believe the eligibility criteria are clear and no revisions are needed.

As a result of the comments, we are finalizing this rule as proposed.

E. Part B Drugs

1. Payment for Biosimilar Biological Products under Section 1847A of the Act

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, also 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: (1) the ASP as determined using the methodology described under section 1847A(b)(6) of the Act 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 (2) 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 section 3139 of the Affordable Care Act regarding payment for biosimilars under the ASP system 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 the CY 2011 PFS final rule with comment

period (75 FR 73393 and 73394) in the November 29, 2010 **Federal Register**. 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 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 monitor the implementation of the FDA biosimilar approval process and the emerging biosimilar marketplace. As biosimilars now begin 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 proposed to amend §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 consistent with section 1847A(b)(8) of the Act), which directs the Secretary to use the weighted average payment methodology that is applied to drugs. We also proposed to amend §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 PFS final rule with comment period. We welcomed comments about these proposals.

We also took 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 (BLA) will be grouped into the same payment calculation for determining the single ASP payment limit. 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 for a biosimilar biological product is determined using the methodology in section 1847A(b)(6) of the Act 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 described 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 also clarified 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 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.

The following is a summary of the comments we received regarding our proposals and related discussion in the proposed rule. In general, a number of commenters opposed a single payment amount for all biosimilars that rely on a common reference product. Commenters included individuals, pharmaceutical manufacturers, patient advocate groups, providers, and members of the House of Representatives. Most of these commenters stated that the CMS proposal will create access issues, and that grouping payment for biosimilar biological products is inconsistent with the statute. Other concerns included a belief that as a result of the proposal, prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to increased costs for biosimilar products. Many of these commenters suggested that CMS determine a payment amount for each biosimilar. However, several commenters also supported CMS's proposal to amend the regulation text effective January 1, 2016. Commenters who supported the proposal also suggested that CMS remain mindful of its policy as the biosimilar marketplace evolves. However, several commenters asked that policy decisions be delayed while issues such as naming conventions and interchangeability standards are finalized by the FDA.

We would also like to remind readers about the scope of CMS's proposals. The proposals and additional discussion encompass payment policy under Medicare Part B; they do not encompass claims processing instructions, coverage policies, clinical decision making and

the clinical use of biosimilars, FDA policies, or payments made by other payers. However, some of these issues overlap with payment policy and we have mentioned them as they pertain to payment policy or specific comments in the more detailed comment responses below.

Comment: Some commenters stated that the proposed rule did not include sufficient explanation of the reasoning behind the proposed change to the regulation text.

Response: Our proposal would amend §414.904(j) to be consistent with a biosimilar payment approach that groups biosimilars with a common reference product. We believe that the proposed change to §414.904(j) would more accurately reflect our interpretation of section 1847A(b)(8)(A) of the Act, which states that the payment for a biosimilar biological product is determined using the methodology in section 1847A(b)(6) of the Act applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as such paragraph is applied to the multiple source drugs described in such paragraph.

Our rationale for this clarification arises from our understanding of both the abbreviated approval pathway for biosimilars and the amendments to section 1847A of the Act to address payment for biosimilars. As further explained below, we believe the approach we are finalizing in this rule is consistent with our statutory authority.

The Affordable Care Act contains two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). Our proposal addressed Part B payment policy, and therefore, focused on section 3139, but section 7002 is also relevant.

Section 3139 of the Affordable Care Act amends section 1847A of the Act to define the term “biosimilar biological product” to mean “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 7002 of the Affordable Care Act defines the terms

biosimilar and biosimilarity for purposes of section 351 of the PHSA to mean (A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

This statutory definition establishes that biosimilar products and their corresponding reference products share a number of significant similarities. That is, the biosimilar biological product and reference product must rely on data from a single biologics license application (BLA) -- the BLA of the reference product; they share high degree of similarity in the active component; and have no clinically meaningful differences in safety, purity, and potency. While we have not stated, nor are we suggesting now, that these similarities must (or even should) drive clinical decision making for an individual patient, they persuade us that our proposed payment policy approach is reasonable.

Because of the degree of similarity that biosimilars share with their reference products, we believe it is appropriate to price biosimilar products in groups in a manner similar to how we price multiple source or generic drugs. In other words, it is reasonable to look to our payment policy for multiple source drugs to guide our policy on payment for biosimilars because multiple source drugs are biosimilars' closest analogues compared to the other categories of drugs and biologics for which we make payment under section 1847A of the Act, such as single source drugs. Of course, we acknowledge the comparison between biosimilars and multiple source drugs is not a perfect one because of the distinct approval processes, statutory definitions, and potentially, the differences in molecular complexity between drugs and biologics. From the perspective of part B drug payment policy, however, we believe that, the abbreviated pathway for biosimilar approval and the abbreviated pathway for generic drug approval have relevant parallels -- such as the approval of a predecessor product (a reference product for biosimilars; an

innovator product for drugs) and the comparison of a product that is being approved through an abbreviated pathway to the predecessor. Further, we believe that biosimilar products and multiple source drugs will have similar marketplace attributes. Although lack of statutory authority prevents us from pricing a biosimilar reference product with biosimilar products, like multiple source drugs, we see biosimilars competing for market share with each other, as well as competing with the reference or innovator product.

Finally, how the payment provision in section 3139 of the Affordable Care Act addresses interchangeability also supports the position that biosimilars can be treated like multiple source drugs. Under section 1847A of the Act, the potential for interchangeability does not factor into how payment is determined for a biosimilar. Neither the definitions in section 1847A, nor the requirements for how payment amounts are calculated treat biosimilars that are interchangeable (and could be potentially be substituted much like generic drugs) differently from other biosimilars. This suggests that Congress contemplated that we should group all biosimilars with a common reference product (in a manner that is similar to multiple source drugs).

Thus, in light of our belief that biosimilars with a common reference product are—for payment policy purposes – analogous to multiple source drugs, we believe that our biosimilars payment policy should mirror payment policy for multiple source drugs to the extent possible. We further believe, as described below, that the statute supports such an approach. We would like to make clear that although our payment policy approach for biosimilars is analogous to our payment policy for multiple source drugs as described in this response, we take no position on whether a biosimilar is completely or partially analogous to its biologic reference product as a clinical matter.

Comment: Many commenters believe that the proposal is inconsistent with the statute and with the regulation text at §414.904(j). Most commenters who provided specific concerns believe that that the use of the singular form of “product” when used to describe payment for

biosimilars in section 1847A of the Act requires that CMS determine separate ASP-based payment amounts for each manufacturer's biosimilar product. Commenters who provided specific concerns quoted some or all of section 1847A(b)(8) of the Act to support their argument that the statute requires that there be a single billing code and payment rate for each biosimilar product. The commenters focused use of the singular form of "product," and said they believe it is a clear indication that the statute requires separate payment for each individual biosimilar product.

Response: We disagree with the commenters and believe that the proposed biosimilar payment approach is consistent with section 1847A of the Act.

We do not believe the use of the singular is dispositive of the issue. The statute directs CMS to apply the payment approach for a given biosimilar biological product in the same manner as such paragraph is applied to drugs described in such paragraph. "Such paragraph" is paragraph (b)(6) of section 1847A of the Act. Section 1847A(b)(6)(A) of the Act states that it applies to all drug products included within the same multiple source drug billing and payment code before setting forth the methodology for determining a volume weighted average sales price for multiple source drugs. The statute also specifies the use of this methodology for determining the average sales prices for single source drugs (under section 1847A(b)(4) of the Act) and biosimilars (under section 1847A(b)(8) of the Act). However, sections 1847A(b)(4) and 1847A(b)(8) of the Act differ in one significant respect; namely, that only section 1847A(b)(8) of the Act includes language that directs the payment determination in paragraph (b)(6) to be carried out in the same manner as paragraph (b)(6) is applied to drugs that are described in paragraph (b)(6). Because all drugs and biologicals paid for under section 1847A of the Act have their ASP-based payment allowances calculated using the methodology set forth in section 1847A(b)(6) of the Act, to give meaning to the phrase that directs that the payment determination be made in the same manner as paragraph (b)(6) is applied to drugs described in paragraph (b)(6), we concluded that the statute

authorizes us to develop coding and pricing for biosimilars in the same manner as for multiple source drugs. Our conclusion is based on the language in section 1847A(b)(6)(A) of the Act, which clearly refers to drug products that are within the same multiple source drug billing code. The paragraph also states that the amount specified (or determined by this approach) is the amount determined using the mathematical calculation in section 1847A(b)(6) of the Act that is applied to all drugs and biologicals paid for under section 1847A of the Act.

We further note that the commenters have emphasized use of the singular form “biosimilar product” to support their statutory interpretation. However, we do not believe whether “product” is used in the singular or plural is the critical point for determining coding and pricing of biosimilars. Rather, we believe the critical point is that Congress is directing us to use the methodology specified in section 1847A(b)(6) of the Act for all drug products that are included with the same multiple source drug billing and payment code to determine coding and pricing for biosimilars.

We believe it is reasonable to interpret the phrase that directs the pricing to be carried out in the same manner as such paragraph (that is, paragraph (b)(6)) is applied to drugs described in paragraph (b)(6), to mean that we have the discretion to calculate an ASP-based payment methodology for grouped biosimilars in the same way that we have discretion to calculate an ASP-based payment methodology for grouped multiple source drugs. CMS’s historical practices have been to develop coding and pricing for programmatic purposes. This approach is consistent with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which required CMS to adopt standards for coding systems that are used for reporting health care transactions, and in October of 2003, the Secretary of HHS delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II Codes (the alphanumeric codes that are typically used in part B drug claims) (Source:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICoding>

[Procedures7-2011.pdf](#) . We believe it is reasonable to believe that Congress is aware of this longstanding policy and that the policy would apply for the pricing and payment of biosimilars. Indeed, had Congress intended a specific and different result than the one we proposed, it could have required a separate payment allowance for each biosimilar biological product. Section 3139 of the Affordable Care Act could have explicitly stated that payment for a biosimilar biological product be determined as provided in section 1847A(b)(4) of the Act. We note that Congress did not specify in the statute how CMS must assign biosimilars to a HCPCS billing and payment code other than direct us to section 1847A(b)(6) of the Act and do so in the same manner as we do for all drug products included with the same multiple source drug billing and payment code.

For these reasons, we disagree with commenters that a proposal to group biosimilar products together for Part B payment purposes and the associated coding approach are inconsistent with the statute. While other interpretations of the statute may be possible, we believe our interpretation is consistent with the statute. We also note that the proposed revised regulation text would not preclude CMS from separating some, or all, of a group of biosimilars for payment (and the creation of one or more separate HCPCS codes) should a program need to do so arise.

Comment: One commenter stated that if Congress had intended that the multiple source drug approach could be used to pay for biosimilars, it would have so specified. This commenter further stated that the detailed direction in the statute that describes the payment for multiple source drugs, including the use of Therapeutic Equivalency ratings, suggests that Congress would have included the same amount of detail for biosimilars had Congress intended for payment to be grouped.

Response: We disagree with this comment. Therapeutic equivalency ratings for drugs have been published by the FDA in the “Orange Book” since 1980 (source:

<http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>). The Medicare Modernization Act, which authorized the use of the ASP payment methodology and defined multiple source drugs for purposes of the ASP payment methodology, was enacted in 2003. We believe that the level of detail in statutory provisions for the payment of multiple source drugs reflects 23 years of experience that Congress could draw on as it carefully crafted a payment approach. Also, the “Orange Book” limits its scope to approved drug products; we would not expect ratings for biological products to be included in this publication.

In contrast, the Affordable Care Act was enacted in 2010, when there was no interchangeability or equivalency pathway available for biosimilar biological products. The “Purple Book”, a list of biosimilar and interchangeable biological products licensed by FDA, was published in 2014. However, no interchangeable products are currently on the market, nor are any expected to enter the marketplace in the next year, and interchangeability standards have not yet been finalized.

We attribute this contrast to the fact that there is insufficient experience or information at this time to create an approach for biosimilars that is as specific as that which exists for multiple source drugs, and therefore, do not believe that the lack of specificity upon which the commenter relies is indicative of Congressional intent to limit CMS’s ability to group biosimilars together for coding and payment purposes.

Comment: Several commenters also cited Senate Committee language that they believe indicates clear Congressional intent to pay for biosimilars separately. (See Senate Committee Report 111-089, pages 225-226 located at <http://www.gpo.gov/fdsys/pkg/CRPT-111srpt89/pdf/CRPT-111srpt89.pdf>.) Commenters focused on the final paragraph of the Committee language as the basis for their opinion about Congressional intent. Specifically, commenters noted that the committee report states that the Committee Bill would allow a Part B biosimilar product approved by the Food and Drug Administration and assigned a separate

billing code to be reimbursed at the ASP of the biosimilar plus 6 percent of the ASP of the reference product. A biosimilar biological product would mean a 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 the Public Health Service Act. The term reference biological product means the licensed biological product that is referred to in the application for the biosimilar product.

Commenters contended that this report's reference to assigning a separate billing code for a biosimilar biological product shows that Congress intended that CMS make separate payment for each biosimilar biological product.

Response: We disagree with these comments for two reasons. First, we believe that the statements commenters characterize as inconsistent with our interpretation of the statute are actually consistent with our interpretation. Second, although commenters focused on one statement in particular, a review of the entire relevant section of the report further indicates our interpretation seems to be consistent with the committee's views.

As noted above, commenters believe that the report indicates that Congress intended biosimilar biological products each to have their own ASP-based payment allowance. However, a closer look at the relevant language indicates that instead, Congress was acknowledging CMS's current coding discretion: "The Committee Bill would allow a Part B biosimilar product approved by the Food and Drug Administration and assigned a separate billing code to be reimbursed at the ASP of the biosimilar plus 6 percent of the ASP of the reference product" (emphasis added). This statement's use of the phrase "would allow" (as opposed to "would require") indicates that CMS has discretion, rather than the obligation, to price biosimilars separately. Moreover, the statement appears to acknowledge that such separate payment would occur only when the biosimilar is assigned its own billing and payment code.

Similarly, the rest of this section of the report supports the notion that biosimilars are

analogous to multiple source drugs. The report indicates the committee's view that the approval pathway to be enacted for biosimilars would be comparable to the approval process for generic drugs, stating:

[t]he new [abbreviated biological] regulatory pathway *would be analogous* to the FDA's existing authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417). Often referred to as the Hatch-Waxman Act, this law allows the generic company to establish that its drug product is chemically the same as the already approved innovator drug, and thereby its application for FDA approval relies on FDA's previous finding of safety and effectiveness for the approved drug.

For these reasons, we believe that contrary to commenters' assertions, our proposed approach to coding and payment for biosimilar biological products is consistent with the Senate Committee report.

Comment: One commenter also suggested that the proposal would be contrary to a 2009 court decision (Hays v. Sebelius) which does not allow Medicare drug payments to be based on the least costly item in a group.

Response: We do not believe that the proposed approach is inconsistent with the Hays v Sebelius ruling on least costly alternatives. In that case, the Court ruled that the Secretary could not rely on section 1862(a)(1)(A) of the Act to pay for one drug product in a given HCPCS code using the lower price for a drug product in a different HCPCS code because it was the "least costly alternative." Instead, the court ruled that the Secretary must either cover or deny payment altogether if the service or item is not reasonable and necessary. As we have explained earlier, we believe that the statutory authority to group biosimilars for payment exists in section 1847A of the Act. Payment for groups of biosimilars will be made under the statutory provision that requires the determination of a weighted average price. Since the approach is consistent with statutory authority for grouping biosimilars and the use of a weighted average calculation (not a partial payment), we believe that our approach is consistent with Hays v. Sebelius.

Comment: Several commenters stated that the proposed Part B payment policy is not consistent with Medicare Part D and particularly Medicaid requirements. Some commenters also stated that the inconsistencies would impact rebate calculations.

Response: Medicare Part B groups and pays for drugs and biologicals differently from Medicare Part D and Medicaid. Drug payment under these programs is authorized by three different parts of the statute, and although they share some similarities, for the most part these payment approaches do not overlap. The different statutory and operational requirements of each program can lead to differences between how drugs and biologicals are treated under each program. The biosimilar payment policies we are finalizing in this rule relate only to the Part B payment requirements described in section 1847A of the Act.

Comment: Some commenters stated that blending of biosimilar product payment amounts is an indication that CMS believes that biosimilars are generic drugs. Commenters expressed concerns about a range of issues related to this position. These concerns focused on provider impact, including negative effects on prescribers' choice, medical record keeping and billing. Some commenters also mentioned that effects on prescribers' choice would include a greater emphasis on cost rather than clinical considerations. Other commenters expressed concerns that brands of biosimilars that may be approved for fewer than all indications approved for the reference product would lead to confusion about the identity of which product was administered to the patient, and make adherence to billing and coverage requirements difficult.

Response: We appreciate that there are differences between multiple source small molecule drugs and biosimilar biological products. The proposals and related discussion in the proposed rule relate only to payment and coding for biosimilar biological products. Thus, although our payment policy for biosimilars is analogous to our payment policy for multiple source drugs, we take no position on whether a biosimilar is completely or partially analogous to its biologic reference product as a clinical matter.

Issues such as the clinical use of drugs and medical recordkeeping are outside the scope of this rule.

We are aware of situations where products with different indications share a HCPCS code;³ however, we are not aware of significant instances of provider confusion resulting from these groupings and therefore, we do not believe that this concern should drive the current policy approach for biosimilars.

Comment: Many commenters discussed how CMS could approach interchangeability between biosimilar products. Positions varied; for example, some commenters suggested grouping interchangeable biosimilars together, others suggested paying interchangeable biosimilars separately. Some commenters also asked that CMS consider blending the biosimilar payment calculation so that the reference product is included in the ASP calculation.

Response: CMS' proposals and related discussion about how biosimilar product ASPs would be grouped did not encompass clinical interchangeability, substitution of biosimilar products or clinical decision making when prescribing these products. While section 7002 of the Affordable Care Act (the Biologics Price Competition and Innovation Act of 2009) outlines specific criteria for a determination of interchangeability, at this point, there are no interchangeable biosimilars products on the market. Thus, we are not addressing whether a product's interchangeability status should be the basis for a different approach to Part B payment

³ For examples: J3489 zoledronic acid injection includes Reclast® (indicated for osteoporosis and Paget's disease of the bone), Zometa® (indicated for hypercalcemia of malignancy, and the treatment of multiple myeloma and bone metastases of solid tumors) and generic versions of both zoledronic acid products; J0153 adenosine injection includes Adenocard® (indicated for the treatment of certain types of supraventricular tachycardia), Adenoscan® (indicated as an adjunct to thallium stress tests for patients who cannot exercise adequately) and generic versions of both adenosine products. Also, certain lyophilized versions of intravenous immunoglobulins (IVIG) have been paid using the HCPCS code J1566 (and its predecessor codes); at this time, the biological products in this HCPCS code do not have the same indications.

in this rule at this time. To the contrary, our proposed approach, which we are finalizing in this rule, would preserve our discretion to group interchangeable biosimilars together for payment purposes in the same manner we will code and pay for biosimilars that do not have a designation of interchangeability under section 7002 of the Affordable Care Act. However, given that no interchangeable biosimilars are currently available, we will consider whether further refinements to our biosimilar payment policy may be necessary as the market develops in the future.

In response to comments recommending that CMS include the reference product in the ASP payment calculation for biosimilars, we note that such an approach is not consistent with section 1847A of the Act.

Comment: Some commenters stated that the payment policy approach may encourage inappropriate interchange between biosimilar products.

Response: We disagree with this comment. We understand that groups of biosimilar products may not have all of the same indications as the reference product in common, all the same indications as other biosimilars within that group, or may have other clinical differences such as fewer than all routes of administration as the reference product. We are not aware of situations where providers have assumed that biological products grouped together for payment purposes are clinically equivalent, or that confusion regarding coverage, billing, coding, or medical records has been a problem.

Comment: A number of commenters also expressed concern about how grouping biosimilar products for payment purposes when they have a common reference product would affect the marketplace. Commenters stated that CMS's proposal would discourage product development and innovation and would affect this new segment for the drug and biological marketplace in a negative manner. Commenters also cited the high risk for biosimilar product manufacturers because of factors such as high product development costs and long product development timelines for biosimilars (compared to small molecule drugs), and suggested that

grouping biosimilar products into a single payment code could lead to a competitive environment that decreases profit margin, forcing manufacturers to leave the marketplace, resulting in less competition, access problems for patients and higher prices. Some of this information appears to have been extrapolated from experience with (small molecule) Part B drugs. However, several commenters who discussed potential differences between biosimilars and drugs suggested that assessing the proposed policy's impact as the market develops and actual experience with this new category of products is gained is a reasonable approach. One commenter believed that the size of the biosimilar marketplace and the regulatory environment created less risk for biosimilar manufacturers than for reference product manufacturers and that CMS's proposed approach would be an incentive for price competition. One commenter suggested that separate pricing of biosimilars was comparable to price protection and that separate pricing is not supported by actual facts. Another commenter stated that separate pricing would reduce competition and would result in a market where biosimilars were sold as branded drugs with small discounts.

Response: We do not agree that our approach to Medicare Part B payment policy will stifle or damage the marketplace. Biological products are heavily utilized in Part B and account for a significant share of spending compared to drugs. According to a GAO report dated October 12, 2012 (GAO-13-46R High Expenditure Part B Drugs, <http://www.gao.gov/products/GAO-13-46R>, pages 6 and 7), Medicare and its beneficiaries spent \$19.5 billion on Part B drugs and biologicals in 2010. The 10 most expensive products accounted for about \$9.1 billion of that amount and 8 of 10 of the highest expenditure Part B drugs were biologicals. Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. To the contrary, we believe there is a strong need for lower cost alternatives to high cost biologicals, and the statute provides an incentive for the development of the biosimilars market by providing for reimbursement that includes a 6 percent add-on of the more expensive reference product's ASP. Competition fosters

innovations that redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries - improving the quality, price, and access. We agree that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development, and we agree with commenters who support future refinements to policy as needed based on actual experience with this new segment of the market.

Comment: Several commenters suggested that CMS consider delaying action on the proposals to allow for FDA policies on issues like naming and interchangeability standards to be developed, and to allow the marketplace to develop.

Response: We disagree with this comment. Issues such as the naming convention and specific interchangeability standards are complicated, may require some time to finalize, and are not directly relevant to Medicare Part B payment policy. Rather, we believe it is important to implement a payment policy for biosimilars now, before the second biosimilar for any reference product becomes available, in order to provide certainty for providers and suppliers who will be billing Medicare for these products in the near term.

Comment: Several commenters stated that the proposed approach is consistent with savings for the beneficiary and sustainability of the Medicare program

Response: We thank the commenters for their support.

Comment: Commenters stated that the proposed approach would negatively impact tracking and safety monitoring because products could not be distinguished on claims. Commenters stated that separate codes are necessary to track the safety of biosimilars and to conduct effective pharmacovigilance efforts, and a few commenters also expressed concerns that clinical outcomes studies would be difficult to conduct. These commenters expressed concern that obtaining data about potential differences in safety and efficacy would be difficult if Medicare paid for all biosimilars that are related to a common reference product the same

amount and used a single HCPCS billing code to indicate that a biosimilar product was administered. However, several commenters suggested other possible mechanisms for using claims data to track biosimilar products, including the use of modifiers.

Response: Pharmacovigilance and the postmarketing assessment of the safety and efficacy of drugs and biologicals are frequently conducted by the FDA. Coding determinations, including the assignment of HCPCS codes, are a part of Medicare payment policy. The FDA's determinations are outside the scope of this rule. However, we agree that it is desirable to have the ability to track biosimilars. We also agree with commenters who suggested that alternative means of tracking biosimilar are possible. We will provide guidance on mechanisms for tracking drug use through information on claims in the near future. Specifically, we are developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance.

Final Decision: After considering the comments, we are finalizing our proposal to amend the regulation text at §414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code. We are also finalizing the proposal's effective date: January 1, 2016.

Comment: Several commenters also acknowledged or agreed with the use of WAC-based pricing during the initial period of sales while an ASP is not available. One commenter understood CMS' discussion to mean that a greater reliance on invoice pricing would result.

Response: We are not changing how pricing determinations by contractors (MACs) are made in situations where national pricing data is not available. We appreciate the comments on our discussion about how biosimilar products will be paid before an ASP is available.

In addition to the comments on biosimilars discussed, we received comments about specific issues pertaining to HCPCS coding and descriptor development such as the use of J codes and Q codes, claims submission and medical record keeping (including the use of NDCs

on Medicare Part B claims), notification of substitution to providers and pharmacy dispensing and substitution activities, coverage policies for biosimilars, effects on other payers, Therapeutic Equivalency determinations based on either the Orange Book or interchangeability determinations based on the Purple Book, and the FDA approval process for biosimilars. Comments on these issues are outside the scope of this rule. Therefore, these comments are not addressed in this final rule with comment period.

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) website 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 website at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html>. Although we discussed the IGI changes to the MFP proxy series in the CY 2016 PFS proposed rule (80 FR 41802) and in this final rule with comment period, in the future, when IGI makes changes to the MFP methodology, we will announce them on our website 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 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 services. 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 are integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams that 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 studies⁴.

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

⁴ Timbie J, Hussey P, Burgette L, et al. Medicare Imaging Demonstration Final Evaluation: Report to Congress. 2014 The Rand Corporation

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. A second 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 a number of sets of AUC developed by different provider-led entities, and an array of CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended Title XVIII of the Act by adding a new section 1834(q) 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 the proposed rule, we primarily addressed 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, 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) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted. 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 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 proposed 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 also proposed to define the term, “provider-led entity,” which is included in section 1834(q)(1)(B) of the Act so that the public had 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 (PLE) 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 the CY 2016 PFS 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 did not include proposals to implement section 1834(q)(3) of the Act in the CY 2016 PFS proposed rule. We needed 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 intend 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. If we were to follow a similar process for CDS as we have for specifying AUC, the initial list of CDS mechanisms would be available in the summer of 2017. 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 PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We did not include proposals to implement section 1834(q)(4) of the Act in the CY 2016 PFS 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. Therefore, we do not intend to require that ordering professionals meet this requirement by January 1, 2017.

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 did not include proposals to implement these sections in the CY 2016 PFS proposed rule, we proposed to identify outlier ordering professionals from within priority clinical areas. Prior clinical areas will be identified through subsequent rulemaking.

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 (as some eligible PLEs have large libraries 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 the CY 2017 PFS rulemaking process, with the benefit of public comments, we will begin to identify 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 proposed to amend our regulations to add a new §414.94, “Appropriate Use Criteria for Certain Imaging Services.”

a. Definitions

In §414.94 (b), we proposed 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 we provide a description of the terms we proposed to codify to facilitate understanding and encourage public comment on the 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 furnished) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the interpretation of the imaging study) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This AUC program only applies in applicable settings as defined in section 1834(q)(1)(D)

of the Act. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any provider-led outpatient setting determined appropriate by the Secretary. The inpatient hospital setting, for example, is not an applicable setting. Further, the program only applies to applicable imaging services as defined in section 1834(q)(1)(C) of the Act. 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 proposed to clarify the definition for appropriate use criteria, which is defined in section 1834(q)(2)(B) of the Act to include only criteria developed or endorsed by national professional medical specialty societies or other PLEs, 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 proposed 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 proposed to define new terms in §414.94(b). A PLE 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 or modified by a qualified PLE, or when a qualified PLE endorses AUC developed by another qualified PLE. A PLE is not considered qualified until CMS makes a determination via the qualification process finalized in this CY 2016 PFS final rule with comment period. We introduced priority clinical areas to

inform ordering professionals and furnishing professionals of the clinical topics alone, clinical topics and imaging modalities combined or imaging modalities alone 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 definitions in §414.94 are important in understanding implementation of the program. Only AUC developed, modified or endorsed by organizations meeting the definition of PLE would be considered specified applicable AUC. As required by the statute, specified applicable AUC 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 proposed 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 proposed to include regulations to implement the first component of the Medicare AUC program – specification of applicable AUC. We first proposed a process by which PLEs (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we proposed to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for specifying 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 of an AUC. Rather, we proposed to establish a qualification process and requirements for qualified PLEs to ensure that the AUC development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

Therefore, we proposed that AUC developed, modified, or endorsed by qualified PLEs will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

To become and remain a qualified PLE, we proposed to require a PLE 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 PLE 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 proposed that the PLE'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 biostatistics, 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 PLE in the development of AUC. We proposed that the PLE must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The PLE 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. In addition, the information must be made available to the public, if requested, in a timely manner.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we proposed that the PLE must maintain on its website 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 recognized 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 proposed 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 website.

It is critical that as PLEs 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 proposed that a PLE'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 website.

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 AUC program, local adaptation of AUC will 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 PLEs can get local feedback at the outset and build alternative options into the design of their AUC. Third, local PLEs 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 proposed that PLEs must apply to CMS to become qualified. We proposed that entities that believed they met 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 PLE. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be qualified PLEs will be posted to our website by the following June 30 at which time all AUC developed or endorsed by that PLE will be considered to be specified AUC. We proposed all qualified PLEs 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 provide information about the CDS mechanism consultation to the furnishing professional, 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 proposed 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 proposed 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 proposed 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 PLE qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence-based criteria may be developed or endorsed by qualified PLEs. Therefore, we proposed 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 proposed 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 proposed 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 PLE 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 PLE 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 proposed 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 proposed definitions of terms necessary to implement the AUC program. We were particularly seeking comment on the proposed definition of PLE as these are the organizations that have the opportunity to become qualified to develop, modify, or endorse specified AUC. We also proposed an AUC development process which allows some flexibility for PLEs but sets standards including an evidence-based development process and transparency. In addition, we proposed the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we proposed to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invited the public to submit comments on these proposals.

The following is a summary of the comments we received regarding our proposals.

Comment: There was disagreement among commenters regarding the proposed definition of PLE. Numerous commenters supported finalization of the proposed definition for PLE. One commenter noted that national professional medical specialty societies were specified in PAMA as an example of a PLE and therefore the definition should encompass such societies. Another commenter requested the agency provide a definition of national professional medical specialty societies. Some commenters requested the definition ensure that provider groups, physicians, and alliances of provider organizations are included. Some commenters requested that the definition of PLE be expanded to include radiology benefit management (RBM) or similar companies, health plans and manufacturers. These commenters stated that providers, physicians and other practitioners are integrally involved if not in control of their AUC development processes. They stated that by including these entities in the definition of PLE, there would be more AUC available in the market (which they believe would yield healthy competition). They also indicated that these entities can move more quickly to update AUCs. Commenters in support of RBMs stated that national professional medical specialty societies had

potential conflicts of interest when developing AUC for use by their own medical specialty as some specialties are paid by performing imaging services. Commenters in support of national professional medical specialty societies state that RBMs had potential conflicts of interest and were incentivized to control costs. Commenters also expressed conflicting opinions regarding the intent of the term “provider-led entities” as used in section 218(b) of the PAMA.

Response: We agree with the commenter that national professional medical societies were identified in the statute as an example of the entities that should fall within the definition of PLE. The proposed definition of PLE explicitly included national professional medical specialty societies, as well as organizations comprised primarily of providers and actively engaged in the practice and delivery of health care. The way that national professional medical societies and other similar organizations are structured, many would not have been considered “actively engaged in the practice and delivery of healthcare” under the proposed definition. This is because national professional medical specialty societies and other similar entities do not, as an organization, deliver care to patients. Therefore, we are modifying the proposed definition of PLE to finalize a definition that focuses on the practitioners and providers that comprise an organization and not on whether the organization, as an entity, delivers care. This approach subsumes national professional medical specialty societies whose members are actively engaged in delivering care in the community and eliminates the need to establish a separate definition for national professional medical specialty societies as they are now an example of a PLE. This will also include alliances and collaboratives of hospitals and hospital system.

Some commenters suggested that physicians and other practitioners are involved in the AUC development process and, therefore, should be considered PLEs. However, we believe the AUC development process typically would be embedded within a larger organization, and the organization as a whole may not be primarily comprised of practitioners. We continue to believe that the statute is intended to focus on the structure of the entire organization, and to require that

it be “provider-led.” We believe that the PLE definition must apply to the organization as a whole, as processes that are embedded within the organization are not the same as a separately identifiable entity. We do not believe the modified definition of PLE that we are finalizing will limit the AUC market or the participation of third parties (such as RBMs) in the AUC development process. There may be opportunity for third parties to collaborate with PLEs to develop AUC.

Comment: Some commenters expressed concerns that the process to become a qualified PLE is more restrictive than section 218(b) of the PAMA requires and could prohibit some organizations with evidence-based AUC from participating in the program, which could limit physician and practitioner choice for AUC consultation.

Response: Section 1834(q)(2)(A) of the Act, as added by section 218(b) of the PAMA, requires that we specify AUC for applicable imaging services only from among AUC developed or endorsed by national professional medical specialty societies or other PLEs. Section 1834(q)(2)(B) of the Act requires that, in specifying these AUC, we must take into account whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on published studies that are reviewable by stakeholders. We believe the process we proposed to identify qualified PLEs is essential to ensuring that we take into account the factors described in the statute.

Comment: Regarding our proposal to require that, in order to be considered a qualified PLE, the PLE’s AUC development process be led by a multidisciplinary team with specific characteristics, some commenters requested that the multidisciplinary team should include more than the minimum three members we had proposed, with some commenters suggesting upwards of 15 members. Other commenters suggested the requirements for the team should not restrict the participation of any qualified participants; in other words, expertise should not be dictated entirely by CMS and teams should have the option to add whomever they determine appropriate.

Still other commenters suggested that CMS should require representation on the multidisciplinary team from primary care, industry, patient advocates and insurers and experts on the imaging study and clinical topic.

Response: We agree that the multidisciplinary team would benefit from additional representation and, more specifically, from representation by primary care practitioners, because a large proportion of imaging orders will be made by primary care practitioners. In response to these comments, we are modifying our proposal to instead require that the multidisciplinary team must have at least seven members including a primary care practitioner. We are also modifying the requirements to clearly state that the required expertise in the clinical topic and imaging service related to the AUC that are being developed must be provided by practicing physicians. These modifications to the multidisciplinary team requirements align with many of the commenters' support for more representation from practitioners in the field.

We agree with the commenters' suggestions that the team should be required to include more members, and that the types of experts required on the team should also be expanded. In addition to primary care, we are also modifying our proposal to require that experts in clinical trial design and statistical analysis be required members of the team. While we do not agree that involvement from industry or patient advocates should be required on the team, we do believe that teams could benefit from dialogue with such stakeholders. In response to the commenters that expressed concern about CMS restricting team participation, we encourage teams to be inclusive and seek members with any other relevant expertise.

Comment: Some commenters expressed concerns regarding the burden associated with the evidence review process we proposed to require for qualified PLEs in the AUC development process. Commenters indicated that the evidence review process that we proposed to require would be expensive, as commissioned systematic reviews are costly, and the process would require a significant amount of time which would be burdensome especially for smaller

organizations. Some commenters suggested replacing “systematic” with “thorough” in describing the evidence review process to avoid unintentionally requiring a commissioned systematic review, and to account for specific methods included in systematic reviews that may not be applicable to all advanced diagnostic imaging studies. One commenter recommended that the cost of systematic reviews and the costs associated with AUC development should be at least partially mitigated by government organizations like CMS, and tax incentives or grant money should be available to medical specialty societies to help offset the costs.

Response: While we understand the commenters’ concerns about the cost and time necessary to comply with the proposed evidence review requirement for developing AUC, we believe that this is a fundamental to ensuring that AUC are evidence-based to the extent feasible as required by section 1834(q)(1)(B) of the Act. We also believe the proposed evidence review process is essential to ensuring that the AUC that are developed can serve their purpose, as indicated in section 1834(q)(1)(B) of the Act, to assist ordering professionals in making the most appropriate treatment decision for specific clinical conditions for individual patients. However, we believe some commenters might have misinterpreted the reference in the proposed rule to a “systematic” review. To clarify, we did not intend to require that the evidence review process must be accomplished by commissioning external systematic evidence reviews or technology assessments. We expect PLEs to undertake evidence reviews of sufficient depth and quality to ensure that all relevant evidence-based publications on trials, studies and consensus statements are identified, considered and evaluated; and that such reviews are reproducible. In response to the commenter that requested financial support in the development of AUC, we note that section 218(b) of the PAMA included no provisions authorizing funding tax incentives, grants, or other financial assistance to PLEs developing AUC.

Comment: Commenters requested clarification on the requirements for modifying and endorsing AUC. Some commenters suggested that qualified PLEs that modify or endorse AUC

should be required to go through the same process required for initial AUC development while other commenters recommended different requirements for modification or endorsement of AUC. Other commenters stated that modification of AUC should not be permitted, and that evidence-based AUC should not be changed to fit local scenarios.

Response: We believe the same process and requirements should apply to the AUC development process for all qualified PLEs, and that modification of AUC should be accomplished using the same process and requirements that apply to the development of AUC. This will ensure that there is documented evidence for the modification. In the proposed rule, we did not intend to differentiate between the process and requirements for AUC development, modification, and endorsement by qualified PLEs. We are clarifying in this rule that this is because a PLE must be qualified to endorse another qualified PLE's AUC. Both entities would have followed the process to become qualified and both entities would be listed on the CMS website as such. Endorsement is not intended to be duplicative. In other words it is not necessary for the endorsing qualified PLE to duplicate the extensive evidence review process performed by the qualified PLE that developed the AUC set or individual criterion.

Regarding local adaption, we believe it is important to fit AUC to local circumstances, while also ensuring application of a rigorous process in doing so. However, only AUC modified by qualified PLEs can become specified applicable AUC.

Comment: Some commenters recommended that CMS identify specific evidence grading methodologies that AUC developers are required to use, for example the GRADE, AHRQ and USPSTF grading systems.

Response: We believe that evidence grading is an essential component of the AUC development process and that AUC developers should have flexibility when working within the requirements we have set forth. In addition, one grading system may be more appropriate for AUC development for a certain clinical condition while another grading system may be best for

another condition. Therefore, we will not require the use of specific grading mechanisms.

Comment: Some commenters requested clarification regarding the meaning of “autonomous governance” specific to the multidisciplinary team.

Response: In proposing that, in order to be a qualified PLE, the PLE’s AUC development process must be led by at least one multidisciplinary team with autonomous governance, we intended to highlight the need for the multidisciplinary team to be independent in its work from influence and oversight by components of the PLE not involved or associated with the multidisciplinary team.

Comment: Some commenters requested the inclusion of a requirement for public comment and/or stakeholder feedback on AUC developed, modified or endorsed by qualified PLEs.

Response: We recognize that some AUC development processes could invite public comment. While we believe this would be appropriate, we do not believe we should establish this as a requirement for the development of AUC by a qualified PLE. We do however believe that public transparency of the resulting AUC and the corresponding evidence base is critical to this program. In order to be a qualified PLE, the PLE must post AUC on their website in the public domain that allows all developed AUC to be reviewed by all stakeholders.

Comment: Some commenters requested further clarification regarding the requirement for AUC to be reviewed and updated. Many had concerns that some PLEs would not update AUC on a frequent enough basis to capture changes in the medical literature. One commenter agreed with requiring regular reviews and updating, and another commenter suggested that review be continuous and should occur on a cycle shorter than 1 year.

Response: We agree that AUC should be reviewed and updated frequently and have included a requirement for qualified PLEs to go through this process at least annually. We believe that qualified PLEs that produce quality AUC should have a process in place to evaluate

the state of the medical literature on an annual basis. These annual reviews will not always result in changes to the AUC, rather, it will ensure that the AUC reflect the current body of evidence.

Comment: Some commenters recommended including processes approved by the National Guidelines Clearinghouse (NGC) as examples of a rigorous evidence-based process, and that we grant provisional approval as qualified to PLEs that have met the NGC inclusion criteria and whose AUC are posted to the NGC.

Response: While the NGC serves as an important repository for clinical practice guidelines, we believe that the CMS application process for qualified PLE status is not overly burdensome as a stand-alone process. We believe our application process is appropriate to assure key aspects of AUC development. We also recognize that PLEs that have their AUC posted to the NGC may find that they are at an advantage in the application process to become a qualified PLE because they have already prepared a package with some similar information.

Comment: One commenter stressed the importance of allowing expert opinion in the AUC development process, especially when relevant studies are limited or lacking in available literature. The commenter also noted the importance of transparency and disclosure of conflict of interest for experts.

Response: The process of AUC development allows for the opportunity for expert opinion, especially as we expect the multidisciplinary team to be populated with such experts. In addition, in the literature review we would expect published consensus papers and similar documents to be identified and be part of the evidentiary review. AUC developers may choose to put their draft AUC into the public domain for comment and receive expert opinion in that manner.

Comment: One commenter recommended that CMS should initiate the AUC development process and use public comment, qualified PLEs and multidisciplinary committees to develop AUC.

Response: Section 1834(q)(7) of the Act clarifies that section 1834(q) of the Act does not authorize the Secretary to develop or initiate the development of clinical practice guidelines or AUC. Additionally, under section 1834(q)(1)(B) of the Act, AUC are defined as criteria only developed or endorsed by national professional medical specialty societies or other PLEs. As such, we do not believe it would be appropriate for us to develop or initiate the development of AUC for purposes of the program under section 1834(q) of the Act.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS website.

Response: At least for the first round of applications for qualified PLEs, we will not be making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient or necessary.

Comment: Some commenters expressed their confusion with the AUC terminology used in the proposed rule. One commenter recommended, for the sake of clarity, using the terms “AUC”, “AUC set” and “required AUC” in the final rule and to revise the definition of AUC accordingly.

Response: We understand that there might have been some confusion, and we have revised the terminology used in this final rule with comment period to provide greater clarity. In general, when we refer to AUC we mean a set or library of AUC, and when we use the term “individual criterion” we are referring to a single appropriate use criterion.

Comment: Some commenters opposed our proposal to specify applicable AUC by first identifying qualified PLEs, and recommended instead that we specify a small group of AUC in order to meet the timeline specified under section 218(b) of the PAMA, and then expanding the list of AUC over time. Other commenters requested that we adopt a phased approach with a focus on AUC for a limited number of clinical conditions that would be used first in larger

hospitals and health systems with gradual expansion to smaller practices.

Response: We believe some of these concerns will be addressed by clarifying our expected timeline which allows additional time for all impacted providers and practitioners to prepare for the AUC consultation program specified under section 1834(q) of the Act. There will be a delay in not only specifying applicable AUC and identifying qualifying CDS mechanisms, but these delays will necessarily result in a delay of the date when ordering practitioners will be expected to report on the Medicare claim form information on their consultation with CDS mechanisms.

Specified AUC must first exist prior to being loaded into CDS mechanisms, and qualified CDS mechanisms must exist prior to consultation by ordering professionals.

We fully anticipate that we will be able to finalize rules and requirements around the CDS mechanism and approve mechanisms through rulemaking in 2017. This timeline will significantly impact when we would expect practitioners to begin using those CDS mechanisms to consult AUC and report on those consultations. We do not anticipate that the consultation and reporting requirements will be in place by the January 1, 2017 deadline established in section 218(b) of the PAMA. Again, we are not in a position to predict the exact timing of this deliverable; however, we do not anticipate that it will take place, conservatively, until CDS mechanisms are established through rulemaking. We do not agree that the requirement to consult with specified AUC should be limited to certain topics or program areas as we believe such consultation will help to improve appropriate utilization across-the-board. We believe that section 218(b) of the PAMA can be rolled out in a stepwise manner to allow adequate time for all providers and practitioners to prepare.

Comment: Some commenters recommended that priority clinical areas be established prior to AUC development and physicians and other practitioners be required to consult AUC only within these areas. Commenters stated priority clinical areas should focus on areas with

AUC for which there are consistently available appropriateness ratings and improved practices resulting from AUC consultation. Other commenters recommended placing limitations on specified AUC, for example limiting the number specified for each clinical condition and limiting specified AUC to those developed by national professional associations.

Response: We do not agree that we should limit the areas in which AUC may be specified. We believe it is more advantageous to specify libraries of AUC because this program is intended to assist ordering professionals in making the most appropriate treatment decisions for a specific clinical condition for an individual with reference to ordering practices for all advanced diagnostic imaging services. However, we believe that the identification of priority clinical areas will allow for physicians and other practitioners to focus their efforts on clinical areas for which there is strong evidence and which may have high impact on patients and society. Our goal is to tie outlier calculations to these high impact clinical areas.

Comment: One commenter requested that we include a process by which AUC developed by national professional medical specialty societies that do not seek to be qualified PLEs can be considered specified applicable AUC and, thereby, incorporated into CDS mechanisms (for example, PLEs with small, specific AUC libraries).

Response: We do not believe it would be appropriate either to allow AUC to be specified that do not meet the development criteria we have established, or to presume that AUC developed by a national professional medical specialty society would meet the requirements of this rule or to develop a separate process for specifying individual appropriate use criterion other than through the PLE qualification process. The requirements for the AUC developed process logically apply whether the PLE is producing only a few subspecialty criteria or hundreds of criteria to covering a large portion of all advanced diagnostic imaging services.

Comment: Some commenters suggested that CMS ensure that PLEs provide all specified AUC to any developers of CDS mechanisms and do so in a similar manner in order to allow

ordering professionals to choose any AUC and any CDS mechanism, and to promote innovation. Other commenters recommended requiring standardization of AUC for the purposes of CDS mechanism integration.

Response: While we are not able to respond fully to these comments in this rule, we believe comments regarding standardization of AUC and CDS mechanisms for purposes of interoperability are very important, and we intend to further consider these comments and address this issue through rulemaking next year.

Comment: One commenter requested that CMS ensure that AUC developers do not use the process to restrict the scope of practice and limit a CRNA's ability to provide comprehensive pain management care.

Response: We are not aware of AUC developed with the goal of limiting the scope of practice for any practitioners. However, should this become a concern, especially to the extent that the limitations might not be evidence-based, then we would take measures to review these AUC, possibly including a review by the MEDCAC of their evidentiary basis.

Comment: One commenter recommended that qualified PLEs that develop AUC for a priority clinical area should be required to produce AUC that reasonably encompass the entire scope of that priority clinical area, so as to ensure that ordering professionals cannot use only a very small number of criteria with the goal of participating in the program as little as possible.

Response: We agree that for a qualified PLE to identify their AUC as addressing a priority clinical area, the AUC must address the area comprehensively; and we are revising our regulations to include language that addresses this concern.

Comment: Some commenters requested clarification about the AUC consultation process. For example, commenters questioned whether ordering professionals are expected to consult all AUC developed by qualified PLEs or just the AUC incorporated into the CDS mechanism they use. Some commenters supported the former approach. Other commenters

recommended that ordering professionals would only be required to consult and report on AUC included in priority clinical areas.

Response: Additional details regarding how this new program will be operationalized and what will appear on the Medicare claim form will be forthcoming in future rulemaking. However, section 218(b) of the PAMA does not expressly limit consultation to only a subset (priority clinical area) of AUC; rather, it is clear that AUC must be consulted for all advanced imaging services. Section 218(b) of the PAMA also recognizes the possibility that ordering practitioners could consult CDS and find no corresponding AUC. We anticipate that more details regarding consultation with CDS mechanisms and claims-based reporting will be released through rulemaking in CY 2017.

Comment: Some commenters expressed concern regarding conflicting AUC and conflicts between AUC and other policies (such as national coverage determinations). Some commenters requested clarification as to a reconciliation process for conflicting AUC and other commenters suggested that specialty societies work together to publish information regarding conflicting AUC.

Response: While we believe that qualified PLEs will be using an evidence-based AUC development process that will reduce the likelihood and frequency of conflicting AUC, we agree that conflicting AUC may be of concern. Conflicting AUC are now highlighted in our rule as an example of situations in which it might be appropriate for CMS and the MEDCAC to review the evidence base. Dramatically conflicting AUC may be a signal that one of them is not evidence-based. The MEDCAC could review the underlying evidence and the committee could discuss whether that evidence supports the conclusions of the AUC thereby exposing any non-evidence-based AUC.

Comment: Some commenters recommended including a mechanism to suspend or remove qualification for PLEs before the periodic requalification process in the event that the

PLE has non-evidence-based AUC and does not take steps to remediate or remove those criteria. Concerns from commenters included that a qualified PLE might fail to follow the process, but continue to have their AUC specified and used by ordering practitioners. Further, there was concern by commenters that non-evidence-based AUC would continue to be used by ordering practitioners for an extended period of time since requalification only occurs every 5 years.

Response: We agree with this comment and have added language to enable us to take steps to remove the qualified status of qualified PLEs that have non-evidence-based AUC within their AUC libraries and do not take prompt measures to resolve or remove the criteria. In addition to this scenario of non-evidence-based AUC, it is important that we have the ability to remove the qualified status from a PLE that fails to meet any of the other requirements set forth in our regulations under §414.94(c) relating to AUC development processes and transparency.

Comment: One commenter suggested that CMS accept applications to become a qualified PLE until March of 2016 rather than requiring them to be submitted by January 1, 2016. Other commenters request a further extension of the deadline, or postponement altogether of the PLE application process.

Response: We are finalizing the proposed deadline of January 1, 2016 for PLEs to apply to become qualified PLEs because we believe it is important that we avoid further delay of AUC specification and program implementation. We note that PLEs will have an annual opportunity to apply to become qualified.

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the 5th year of approval will receive a determination prior to the start of the qualified PLE's 6th year. Therefore, the cycle of approval for qualified PLEs is

every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017

Year 2 = July 2017 to June 2018

Year 3 = July 2018 to June 2019

Year 4 = July 2019 to June 2020

Year 5 = July 2020 to June 2021 (reapplication is due by January 1, 2021)

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if it appears that qualified PLEs are not maintaining compliance with our requirements for AUC development, we could reevaluate the requalification timeline in future rulemaking.

Comment: One commenter recommended listing all qualified PLEs on the CMS website.

Response: We agree with this comment and will list all qualified PLEs on the CMS website.

Comment: One commenter recommended a limit to the number of PLEs that can be qualified.

Response: We do not, at this time, believe it is necessary to limit the number of PLEs that can be qualified. If a PLE becomes qualified and is developing evidence-based AUC we believe they should have the opportunity for their AUC to become specified.

Comment: We received numerous comments regarding how to identify priority clinical areas. Some commenters recommended that CMS initially focus on a small number of high volume services. One commenter recommended limiting the priority clinical areas to only those with a strong evidence base rather than areas reliant on consensus opinions. Another commenter recommended including areas where a large gap exists between currently available AUC and studies that are ordered in the Medicare program (for example muscular-skeletal conditions, abdominal conditions). One commenter recommended that the priority clinical areas should clearly define cohorts of patients with common disease processes or symptom complexes. One commenter recommended that qualified PLEs identify the priority clinical areas or that CMS should accept proposals from qualified PLEs when identifying these areas. One commenter suggested that CMS consider imaging studies that have had high utilization rates over the past 10 years, conditions for which AUC have been most recently adopted where significant inappropriate use may still exist, and simple, common conditions.

Response: We appreciate these recommendations and believe that the proposals that we are finalizing will allow for consideration of varying elements in identifying priority clinical areas. We expect to propose the first priority clinical areas in next year's PFS rule based on stakeholder consultation, and hope to receive further, more specific public comments at that time.

Comment: Some commenters suggested that CMS identify a substantial number of priority clinical areas to ensure enough data are available to calculate outlier ordering professionals with statistical significance. One commenter recommended that, for the purpose of outlier identification, these areas should include those where there is wide clinical variance in appropriate ordering patterns.

Response: We appreciate these suggestions and will consider them when identifying proposed priority clinical areas.

Comment: Many comments strongly supported the proposed transparency requirements for qualified PLEs. Commenters supported the public posting of AUC, references to the information considered in developing AUC and AUC development, and the review and updating processes to qualified PLE websites. One commenter recommended posting all AUC development information to a website hosted by CMS. Another commenter requested clarification about acceptance of alternate means of making the information public (for example, hard copies upon request, electronically upon request, but not posted in full to the website).

Response: We agree that the transparency requirements are important and essential to this program. Public posting of the AUC and other required information to each PLE's website is required; and it will not suffice to make the information available in other, less accessible and transparent ways. It is our goal that the information be easily accessible and reviewable by all stakeholders. We do not anticipate posting this information on a CMS website as each qualified PLE retains responsibility for public posting of the required information.

Comment: Most commenters supported our proposed policies on transparency and conflicts of interest for multidisciplinary team members. Some commenters recommended further strengthening these requirements to incorporate references to AUC-related activities or relationships specific to commercial, non-commercial, intellectual, institutional, patient/public arenas. Other commenters recommended requiring the exclusion of team members with any significant conflicts of interest. Some commenters recommended that we impose transparency requirements for individuals and organizations at the commercial level specific to CDS mechanism sales/marketing, licensing relationships and advisory board memberships. One commenter requested clarification regarding conflict of interest requirements for entities that endorse AUC.

Response: We agree that transparency and disclosure of conflicts of interest is essential for multidisciplinary team members, and we are clarifying in this final rule with comment period

that these requirements apply to the team and to any other party involved in developing AUC including the qualified PLE itself. We disagree with the commenter's suggestion to categorically exclude through our regulations team members for whom there is a conflict of interest as those individuals may also have the greatest knowledge base for particular issues. Some conflicts may be unavoidable, and we believe transparency and disclosure will go far toward promoting objectivity. We believe that qualified PLEs should use their judgment to establish thresholds where certain conflicts would result in recusal or removal of an individual from the multidisciplinary team. We are aware that there are a number of existing templates, thresholds, and mechanisms that might reasonably apply to address conflicts of interest. We might address this issue further, and standardization of the treatment of conflicts could evolve through our annual rulemaking process. At this time we believe it is appropriate for conflicts to be disclosed and for the PLE to have a reasonable process in place to identify and address them. The final rule with comment period also provides for the information to be documented and available to the public upon request for a period of 5 years.

Comment: One commenter requested that transparency requirements specific to AUC and AUC development processes be balanced with "intellectual property protection for evidence-based content produced by commercial entities..." which could involve a process by which interested parties request access to criteria while intellectual property is protected. One commenter stated that CMS should not require public release of evidence-based content published under copyright protection.

Response: We support and have received strong support for the required public disclosure of these processes and resulting content. Transparency is essential to ensure all patients and stakeholders can review and understand how and why AUC are developed, and to which types of patients they do and do not apply. Making this information public is particularly important for ordering professionals when they are selecting the qualified PLEs and CDS

mechanisms that best address their practice needs. CDS mechanism developers and qualified PLEs may need to enter into agreements for AUC to be loaded into the mechanisms and used by ordering professionals.

Comment: One commenter recommended that we adopt a requirement for AUC developers to disclose any participating medical specialty societies that do not endorse the AUC being developed and the rationale for their not endorsing.

Response: PLEs may choose to list which medical specialties societies agree with their AUC and which ones do not. However, we do not believe it would be appropriate for us to require this disclosure or explanation. By having AUC in the public domain, any organization may respond to the AUC and state their agreement or disagreement in any format they determine is appropriate.

Comment: Many commenters expressed significant concerns regarding the implementation timeline set forth in section 218(b) of the PAMA. Commenters questioned whether it is feasible or reasonable to meet the January 1, 2017 deadline to require consultation by ordering professionals with CDS mechanisms given that we do not anticipate finalizing requirements for CDS mechanisms until rulemaking for the CY 2017 PFS and CDS mechanism developers and ordering professionals will need 12-18 months to incorporate the requirements into clinical practice.

Response: We understand these concerns and agree that the timeline set forth in section 218(b) of the PAMA is difficult to meet. As such, we will delay implementation of certain AUC program components including the requirement for consultation with CDS mechanisms. Consultation with a CDS mechanism will not be required on January 1, 2017 because we do not expect to have approved CDS mechanisms by that date. Although we will develop our plans through further rulemaking, at this time, we do not expect to have approved CDS mechanisms until approximately summer of 2017. In that event, consultations with CDS mechanisms could

not take place on January 1, 2017.

Comment: Some commenters supported maintaining the timeline set forth in the PAMA for AUC program implementation. One commenter stated that their organization was able to comply with the timeline. Some commenters also recommended using subregulatory guidance and requests for information (RFIs) outside of rulemaking to meet the timeline set forth in the PAMA.

Response: We appreciate the willingness and enthusiasm of these stakeholders in moving quickly forward in AUC program implementation; however, we believe that it is important to take a stepwise approach to implementation and to establish the components of this program as proposed through notice and comment rulemaking. This approach will ensure that we fully comply with requirements set forth in PAMA for stakeholder consultation, and that we develop a sound implementation plan. We will continue to engage with stakeholders to inform development of future AUC program components and we will consider using an RFI to help inform the next rulemaking cycle.

Comment: Many commenters encouraged CMS to engage in continued stakeholder interactions and dialogue for all aspects of the AUC program. Commenters particularly advocated for continued stakeholder involvement as we develop CDS mechanism requirements during the CY 2017 rulemaking cycle. Some commenters recommended more engagement with professional societies representing ordering physicians and one commenter suggested representation of ordering and primary care physicians if a MEDCAC is convened.

Response: We will continue to have an open-door policy and engage all stakeholders to develop and refine the AUC program. Not only is stakeholder consultation a requirement of PAMA, but we have found these interactions to be highly informative and critical in building this program.

Comment: Many commenters offered suggestions regarding the CDS component of the

AUC program. Commenters identified specific areas of importance for CMS to focus on such as interoperability of CDS mechanisms and electronic health records (EHRs) and the relationship between AUC developers and CDS mechanisms. Commenters also cautioned against a roll out of this component that would not allow sufficient time for CDS mechanisms to comply with the requirements yet to be established in rulemaking or the incorporation of AUC consultation through approved CDS mechanisms into clinical practice. Commenters further requested that CMS address the CDS mechanisms as soon as possible, potentially via avenues outside of the rulemaking process, to account for the short implementation timeline specified in section 218(b) of the PAMA. Commenters provided important and thoughtful recommendations and feedback regarding the CDS component of this program.

Response: We understand the interest in, and concerns expressed about the need for more information and details regarding the CDS mechanism requirements and incorporation into clinical practice; however, as discussed in our proposal, we anticipate that details regarding CDS mechanisms will be the focus of rulemaking during 2016 for the CY 2017 PFS. We appreciate these comments and will use them to inform development of future proposals. We will also continue to consult and interact with stakeholders. We note again that we do not expect that the AUC consultation through approved CDS mechanisms could be required on January 1, 2017.

Comment: Some commenters expressed concern regarding the burden placed on furnishing professionals in reporting on ordering professionals' compliance with AUC consultation. One commenter recommended that the furnishing professional should only be required to report on the claim whether or not the ordering professional consulted AUC.

Response: Under section 1834(q)(4)(B) of the Act, the furnishing professional is required by statute to include information on the claim (for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system) that identifies what qualified CDS mechanism was consulted by the ordering professional, whether the service

ordered would or would not adhere to that AUC, or was not applicable to the service, and the NPI of the ordering professional.

Comment: Some commenters requested clarification about allowing variations in AUC based on local populations and circumstances and cautioned that allowing exceptions to specified AUC could work against the goal of the AUC program. Many commenters supported flexibility in allowing variations based on local populations and circumstances, but some commenters suggested that processes for variations should still meet the AUC program requirements and should be rare.

Response: We believe that allowing for variations in AUC based on local circumstances is important to ensure that AUC consultation can be incorporated into clinical practice throughout the country. We agree that local variations should still meet the program requirements to ensure that the evidence to support modification is evaluated and graded and only performed by qualified PLEs.

Comment: Some commenters noted that section 218(b) of the PAMA allows for an exception to the requirement to consult AUC in the case of certain emergency services, but our proposal states that AUC applies to various settings including the Emergency Department. Commenters stated that this ambiguity could cause a delay in the delivery of emergency services to patients and requested clarification on the application of the AUC program in emergency departments and exceptions for certain emergency services.

Response: We understand the confusion and will take these comments into account as we further develop our policies on exceptions in the case of certain emergency services. We anticipate addressing this issue in rulemaking for the CY 2017 PFS.

Comment: One commenter requested clarification on whether mobile, free-standing high tech radiology units are subject to this program.

Response: Whether the equipment is mobile or fixed, the requirement to consult AUC is

based on whether the service at issue is an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system. Applicable imaging services include, in general, advanced diagnostic imaging services for which AUC are publicly available without charge. Applicable settings include a physician's office, hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. Applicable payment systems include the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system. Although we anticipate developing further details regarding these specifications through future rulemaking, we believe the statutory specifications are fairly clear as to the services for which ordering professionals will be required to consult, and report on their consultation of, AUC. We believe the commenter can make a good preliminary assessment as to whether its services fall within these specifications.

Comment: One commenter stated that the proposed AUC program will have unintended consequences on ordering professionals and creates a burden for these practices without the promise of improved care. This commenter stated that some professional societies were not consulted in development of section 218(b) of the PAMA.

Response: AUC consultation by all advanced diagnostic imaging ordering professionals is a requirement under section 218(b) of the PAMA. We are developing this program with extensive stakeholder consultation and input to ensure that the program is implemented in a manner that does not create excessive burden for ordering professionals; yet we recognize that there unavoidably will be some underlying burden for ordering professionals in consulting AUC and reporting on that consultation.

Comment: Some commenters recommended that physicians and hospitals already involved in payment reform models be exempt from reporting requirements for ordering

professionals under this program.

Response: Section 218(b) of the PAMA does not include a provision for exceptions for participants in payment reform models. We will consider whether there is authority within the context of such models to consider developing exceptions for model participants.

Comment: Some commenters requested clarification regarding the use of non-evidence-based AUC, particularly when evidence-based AUC are available. Commenters suggested that non-evidence-based AUC may be more prevalent in the everyday practice of medicine.

Response: Section 218(b) of the PAMA requires that, to the extent feasible, AUC must be evidence-based; and we are including that requirement in the AUC development process. However, the process allows for the spectrum of the hierarchy of evidence to be used as part of the systematic review. AUC based on lower levels of evidence will be apparent as each appropriate use criterion posted to the PLE website would include the level of evidence for each of the decision node.

Comment: Some commenters expressed support for our proposal to identify non-evidence-based AUC through annual rulemaking and encourage public and stakeholder input in the process. One commenter suggested requiring all non-evidence-based AUC to be reviewed by the MEDCAC. One commenter recommended that CMS define and implement an additional auditing process that could be used to identify abuses and systematic failures.

Response: We are finalizing this proposal with additional language stating that conflicting AUC will be incorporated into the process for addressing non-evidence-based AUC. The MEDCAC may be convened to review these AUC. If a non-evidence-based appropriate use criterion is identified by the MEDCAC and the qualified PLE fails to revise the criterion to reflect the evidence then we may take action regarding the qualified PLE's status. In other words, we may determine that qualification should be reconsidered outside the 5 year reapplication process. We have not created additional auditing processes beyond those that we

already possess. We could consider this in future rulemaking if the agency and MEDCAC become overwhelmed by the volume of non-evidence-based AUC.

Comment: One commenter requested incorporation of a process for hardship exemptions to consider factors that might prevent or delay institutions from meeting the requirements of the AUC program.

Response: We will address the significant hardship exemption (section 1834(q)(4)(C)(iii) of the Act) in future rulemaking, and anticipate doing so in rulemaking for the CY 2017 PFS.

Comment: Some commenters recommended that ordering professionals who follow AUC that are developed by internationally-accepted methodologies should not have to complete prior authorizations related to that treatment. One commenter cautioned against including new care improvements in the identification of outliers as clinical practice will continue to change. One commenter requested that the CMS definition for outliers and mechanisms used to identify and penalize outliers must have the necessary flexibility to account for differences in volume of advanced imaging studies due to the composition of a physician's practice.

Response: We will address outlier identification and the prior authorization component of this program in future rulemaking.

Comment: Many commenters expressed concerns about the absence of claims processing instructions and reporting requirements for AUC consultation in our proposal, and the short time frame between publication of the CY 2017 PFS and the PAMA deadline for consultation with CDS mechanisms. Some of these commenters included suggestions for these instructions and reporting requirements.

Response: As discussed in the proposal, we anticipate addressing claims reporting requirements during the CY 2017 PFS rulemaking process. The deadline for consulting CDS mechanisms and reporting such consultations on Medicare claims will be delayed for a year consistent with our proposals in the proposed rule.

Comment: Some commenters believed that our proposal addressed problems encountered in the MID. One commenter specifically noted that the proposal accomplished this by: (a) expanding on the AUC definition to identify AUC as link between presenting clinical conditions and appropriate imaging services, not just based on imaging service; (b) correctly stressing the importance of integration of the CDS into clinical workflow; and (c) recognizing the importance of flexibility in implementing best practices given local circumstances. Other commenters stated that the proposal ignored some recommendations from the MID, specifically the recommendation to include guidelines from entities other than national specialty societies as the MID noted that societies “have a vested interest in advising that imaging be ordered.”

Response: We have attempted to balance the findings of the MID with the statutory requirements by specifying libraries of AUC as opposed to individual criteria, and we hope that our transparency and conflict of interest requirements will address concerns that commenters had regarding conflict of interest of AUC developers. We also believe that lessons learned in the MID will benefit CDS mechanism development, and we encourage additional comments in that regard in the future.

Comment: One commenter requested confirmation that the AUC program will only be applicable to Medicare FFS, and not Medicare Advantage.

Response: This program is applicable only to services for which payment is made under the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

Comment: One commenter suggested that AUC should fit under the Merit-Based Incentive Payment System and should not be a stand-alone program.

Response: We do not believe, at this time, that it would be feasible for this program to be incorporated under other quality or value-based programs. However, we could explore whether there are opportunities for consolidation in the future.

In response to comments, we are making some changes to our proposals as well as finalizing most aspects of the policies as they were proposed in the CY 2016 PFS proposed rule.

We are finalizing the majority of definitions as they were proposed. However, based on public comments, we are changing the definitions of AUC, PLE and priority clinical area.

We proposed to define AUC as criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering 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 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). We are revising the last two sentences of the definition in response to public comments that expressed confusion regarding the AUC terminology used in our proposal. We have also revised related language throughout the final regulation accordingly.

We proposed to define PLE as 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. We are revising the definition of PLE to refer to organizations comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. The definition of PLE will retain the direct reference to national professional medical specialty societies, and other organizations like them are now subsumed within the definition.

This definition of PLE will include health care collaboratives and other similar organizations such as the National Comprehensive Cancer Network and the High Value Healthcare Collaborative. While this is not a dramatic change from the proposed rule, the focus is now on the role of the members that comprise the organization and not the function of the

organization itself. This definition aligns with the statute in that national professional medical specialty societies are given as an example of a PLE. Under the proposed definition, these societies were expressly specified as PLEs. It is not the function of the society to deliver care but rather their members are actively engaged in practicing medicine in the field. This final definition appropriately encompasses these organizations and others that are comprised of providers or practitioners who care for patients.

We are also modifying our proposed definition of priority clinical area. We proposed to define priority clinical area as 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. We are changing the language to better describe the breadth of clinical areas that may be the focus of priority clinical areas. The finalized definition better reflects that priority clinical areas may identify clinical conditions, diseases or symptom complexes and their associated advanced diagnostic imaging services. This definition will allow the priority clinical areas to better align with the variety of clinical situations for which a patient may present to the ordering practitioner.

In response to the comments we received regarding the role of endorsement of AUC, we are adding a new §414.94(d) to the regulations. This new section clearly describes the role of endorsement. We note that only a qualified PLE may provide endorsement of AUC. Further, qualified PLEs may only endorse the AUC of other qualified PLEs. Independently, each organization must have been qualified, and therefore, we do not envision participation by CMS in the endorsement relationship. The primary function of endorsement is for qualified PLEs to combine their AUC to create a larger, more clinically encompassing library. For example, one qualified PLE may focus on developing AUC related to neuroimaging, another may focus on developing AUC related to abdominal imaging. The endorsement relationship gives recognition to this type of collaboration.

While we are finalizing the requirements for developing or modifying AUC as proposed (with the exception of grammatical, non-substantive changes for regulatory consistency) in §414.94(c)(1), we provide clarification in this final rule with comment period around what is expected regarding a systematic literature review as public commenters did not indicate a consistent understanding of this concept. To clarify, the evidence review requirement does not mean that PLEs must commission external systematic evidence reviews or technology assessments. We expect many organizations will undertake their own systematic evidence review to ensure all relevant evidence-based information is considered and evaluated. The literature review must be systematic, reproducible and encompass all relevant literature related to the specific imaging study. Ideally, the review would include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the PLE must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. We do not require that a particular methodology be used as there may be certain methodologies better suited to some evidentiary assessments than others.

For consistency with regulatory structure, we have revised the proposed language throughout §414.94(c) to more clearly represent the responsibility of the PLEs seeking qualification in demonstrating adherence to AUC development requirements under this section.

Based on public comments, we are changing the requirements for the multidisciplinary team that must be used in the AUC development process. We proposed 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. While we proposed to require a smaller team, we are finalizing §414.94(c)(1)(ii) to state that a qualified PLE must utilize at least one multidisciplinary team with autonomous governance, decision making and accountability for

developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner (as defined in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act), one expert in statistical analysis and one expert in clinical trial design. A given team member may be the team's expert in more than one domain. A team comprised in this manner and at this size better encompasses the expertise and the dedication needed to develop quality AUC. We encourage such teams to be larger where appropriate, and to include experts in medical informatics and quality improvement. These experts should contribute substantial work to the development of the criteria, not simply review the team's work. Teams may also consider involving other stakeholders.

Based on public comments in support of frequent review of AUC, we are adding language to §414(c)(1)(vii) to require at least annual review by qualified PLEs of their AUC.

In addition, since new §414.94(d) has been added to clarify the role of qualified PLE endorsement, the term endorsement has been removed from §414(c)(1)(ii) as it relates to the multidisciplinary team. Since only qualified PLEs can provide endorsement, these qualified PLEs have already demonstrated they meet the requirements of §414.94(c)(1)(ii).

We have added language to the conflict of interest disclosure requirement in §414.94(c)(1)(iii) to make clear that the conflict of interest processes and disclosures would apply not only to members of the multidisciplinary team but also the PLE and any entity that participated in the development of AUC.

In addition, and in response to comments, we have included that the conflict of interest process put in place by the PLE must also include processes to recuse or exclude members of the multidisciplinary team where appropriate. This language was not included in the proposed

language of §414.94(c)(1)(iii). We are finalizing conflict of interest language in §414.94(c)(1)(iii) and §414.94(c)(1)(iii)(A) and §414.94(c)(1)(iii)(B).

We are finalizing language to clarify that CMS will perform a review of each PLE's application for qualification. We have added "for review" to §414.94(c)(2)(i) to make it clear that PLEs must submit an application to CMS for review that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section.

We proposed the requalification timeline in §414.94(c)(2)(v). We revised the language and finalized two sections to clarify the requirements related to qualified PLE reapplication.

In the proposed rule we stated that PLEs, on their website, must identify when they have AUC that address a priority clinical area. Section 414.94(c)(1)(iv) included that, if relevant to a CMS identified priority clinical area, such a statement must be included. We have expanded this requirement and created §414.94(c)(1)(v) to include this requirement. This ensures that the AUC are broad enough in scope that an ordering professional could use those AUC to satisfy the priority clinical area.

Section 414.94(f)(3) has been added to clearly specify that CMS will consider information related to a PLE's failure to correct non-evidence-based AUC to determine whether CMS should terminate the PLE's qualified status, and that the information would be used during the PLE's re-qualification review.

To broaden the scope of which potentially non-evidence-based AUC may be reviewed by the MEDCAC, we have revised the language so as not to be limited to reviewing AUC that correspond to priority clinical areas. We proposed §414.94(e)(1) to state that 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. We have added language to §414.94(f)(1) that gives priority to AUC that correspond to priority clinical areas but does not limit review to such. In this section, we have also identified

that conflicting AUC may receive priority in MEDCAC review.

We thank the public for their comments and believe the changes based on these comments have improved the requirements and process that we will follow to specify AUC under this program for advanced diagnostic imaging services. Following the publication of this final rule with comment period, we will post information on our website for this program accessible at www.cms.gov/Medicare/Quality-Initiatives/Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program.

H. Physician Compare Website

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 website 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 website 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 website, we have continued to build on and improve Physician Compare, including a full redesign in 2013. Currently, website 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.

We received several comments about the enhancements made to the Physician Compare website and the data currently on the website.

Comment: Several commenters noted the improvements made to the Physician Compare website, as well as appreciation for the transparency and easy-to-use, comprehensive information available on the site to aid consumers in making informed health care decisions. Some commenters suggested CMS make continued improvements to the Intelligent Search functionality particularly around finding professionals other than physicians and including additional specialty labels for Advanced Practice Registered Nurses (APRNs) and allied health professionals. One commenter encouraged CMS to continue its discussions on how to make the website fully accessible and useable by persons with a wide range of disabilities, including vision, sight, and cognitive challenges.

Some commenters provided suggestions for additional information to publicly report on Physician Compare, including whether a health care professional offers patients online access to their health information, specialist-specific training and certification data, and other qualifications, such as the Certified Medical Director designation and the Certificate of Added Qualifications in Geriatric Medicine, testimony of enhanced comprehensive care services, expanded access or non-traditional hours, and care management and coordination information. One commenter urged CMS to include information about accessibility.

Response: We are committed to continuing to improve the site and its functionality to ensure it is a useful resource for Medicare consumers, including information that can help these consumers make informed health care decisions. We appreciate the recommendations for specific information to consider for inclusion on the website and the recommendations regarding usability. CMS works to ensure the website is accessible to all users and we will continue to

ensure Physician Compare meets accessibility standards. Also, we will be sure to consider the specific recommendations received for possible information to add for future inclusion, if appropriate. We are continually working to improve and enhance the Intelligent Search functionality, and we will continue to do so. Currently, APRNs are searchable on the website through this functionality, but we will continue to work with stakeholders to further improve upon this option.

Comment: Some commenters expressed concerns with the accuracy of demographic data including addresses, education, and hospital affiliation. Several commenters urged CMS to continue to work to correct any demographic data errors prior to expanding public reporting on the website. Other commenters requested we implement a streamlined process by which professionals can confirm or correct their information in a timely manner. Some commenters urged CMS to ensure that updates made in PECOS are reflected on Physician Compare within 30 days. One commenter suggested a new mechanism for real-time address updates on the website and several other commenters suggested a process that allows stakeholders to review and correct information on the site.

Response: We appreciate the commenters' feedback regarding concerns over the accuracy of the demographic information currently available on Physician Compare. We are committed to including accurate and up-to-date information on Physician Compare and continue to work to make improvements to the information presented.

The underlying database for Physician Compare is generated from PECOS, as well as fee-for-service (FFS) claims, and therefore, it is critical that physicians, other health care professionals, and group practices ensure that their information is up-to-date and as complete as possible in the national PECOS database. Currently, the most immediate way to address inaccurate PECOS data on Physician Compare is by updating information via Internet-based PECOS at <https://pecos.cms.hhs.gov/pecos/login.do>. Please note that the specialties as reported

on Physician Compare are those specialties reported to Medicare when a physician or other health care professional enrolls in Medicare and are limited to the specialties noted on the 855i Enrollment Form. Also, all addresses listed on Physician Compare must be entered in and verified in PECOS. There is a lag between when an edit is made in PECOS and when that edit is processed by the MAC and available in the PECOS data pulled for Physician Compare. This is time necessary for data verification. Unfortunately, this means there is a delay. We are continually working to find ways to minimize this delay, and, in the past year we reduced the data refresh cycle from monthly to bi-weekly to further improve data timeliness.

To update information not found in PECOS, such as hospital affiliation, professionals should contact the Physician Compare support team directly at PhysicianCompare@Westat.com. Information regarding how to keep your information current is also on the Physician Compare Initiative page on [CMS.gov \(\\westat.com\dfs\PHYSCOMPARE\Proposed Rule and Public Comment\2016 PFS Rule\Final Rule\CMS.gov\)](https://www.cms.gov/westat.com/dfs/PHYSCOMPARE/Proposed%20Rule%20and%20Public%20Comment/2016%20PFS%20Rule/Final%20Rule/CMS.gov).

We appreciate the suggestions for alternative ways to update demographic data. However, PECOS is the sole verified source of Medicare information, and thus, some information must come to Physician Compare through PECOS. We are aware of PECOS' limitations and recognize that PECOS' primary purpose is not to provide up-to-the-minute information for a consumer website. For these reasons, we completely overhauled the underlying database and began using Medicare claims data to verify the information in PECOS in 2013. Because of this, the data are significantly better today than they were prior to the 2013 redesign and we will continue to work to find ways to further improve the data and the process of receiving and updating the data. We strongly encourage all professionals and group practices listed on the site to regularly check their data and to contact the support team with any questions or concerns. Together, we can continue to make the website better.

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 website 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 website, 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 website 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 received comments regarding this previously finalized policy related to quality program participation.

Comment: A commenter urged CMS to reconsider publicly reporting participation in the Medicare EHR Incentive Program due to ongoing issues related to the program. Some commenters suggested adding indicators for individual health care professionals or group practices who participate in a QCDR, participate in a quality improvement registry for other services, or participate in other voluntary quality improvement initiatives. One commenter requested that quality program participation be reported at an aggregated level rather than by each program. Another commenter noted that consumers are not familiar with quality initiatives, so an indicator should be tested with consumers.

Response: We appreciate the commenters' feedback, and we will take the suggestions provided regarding indicators into consideration for possible future enhancements. However, since participation in the EHR Incentive Program is currently included on Physician Compare, as

previously finalized, and consumers find this information interesting and helpful, we are going to continue including an indicator for participation in the EHR Incentive Program on the website. Quality initiatives include a variety of programs with distinct goals. Therefore, we will continue to include an indicator for each program. We also understand that explanatory language helps inform health care consumers as they use the website. We currently test all information included on the website with consumers to ensure they understand the information provided. We recently focused testing on the quality initiative indicators. Plain language updates are forthcoming as a result of this testing. We will continue to work to ensure that the language included on Physician Compare helps users understand these quality initiatives and use the information provided appropriately and accurately.

We continue to implement our plan for a phased approach to public reporting performance information on the Physician Compare website. 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 website, 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.

Comment: We received one comment commending CMS for including Diabetes quality measures.

Response: We appreciate the commenter's support, and will continue to publicly report relevant quality measures that meet the public reporting standards.

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 website, 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 measures available for public reporting, including both group and individual EP level measures—regardless of reporting mechanism, only those 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 and that prove to resonate with consumers 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 received several comments regarding the public reporting standards we have established for Physician Compare. The following is a summary of the comments received about the public reporting standards.

Comment: Many commenters supported only publishing on Physician Compare those measures that meet the public reporting standards. Several commenters urged CMS to carefully assess if all measure data are sufficiently reliable and valid for public reporting before posting the data. One commenter requested CMS to publish the results of validity and reliability studies, as well as the methodology for choosing measures prior to posting on Physician Compare. Several commenters are concerned that measures related to patient behavior, preferences, or abilities do not provide a statistically valid portrayal of a physician's performance and should not be published unless the data is appropriately risk adjusted. Several other commenters also strongly urge CMS to move forward with expanding its risk adjustment methodology to account for these patient behavior, preferences, or abilities that may influence quality and performance measurement. Many commenters supported not publicly reporting first year measures. Several commenters requested flexibility, noting that some measures may be appropriate for public reporting immediately while others may need additional time to mature. A few commenters recommended a three-year delay in public reporting of all new measures to enable professionals to accurately report the measures and to account for measure testing and validity.

Response: We appreciate the commenters' feedback, and understand the various concerns raised. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that the data posted on the website are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. We understand that this information is complex, and are committed to providing data on Physician Compare that are useful to beneficiaries in assisting them in making informed health care decisions, while being accurate, valid, reliable, and complete. We will closely evaluate all quality measures under consideration for public reporting on the website to ensure they are meeting these standards. We will also only post data that meet this standard of reliability

regardless of threshold, and regardless of measure type. Should we find a measure meeting the minimum threshold to be invalid or unreliable for any reason, the measure will not be reported. We will also not publicly report first year measures to allow health care professionals to learn from the first year of reporting and to account for measure testing and validity. 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. We also continue to encourage measure developers to build in risk adjustment at this level. We will continue to analyze the measures available for public reporting to ensure that risk adjustment concerns are taken into consideration. This is true for all measures, clinical quality, and patient experience. Again, all measures must meet the public reporting standards established for Physician Compare to be included on the website.

As mentioned above, in previous rulemaking, we have outlined some of the types of reliability studies that are conducted for measures (79 FR 67764 through 79 FR 67765). Additional information is also shared annually via our Technical Expert Panel (TEP) summaries which can be found on the Physician Compare Initiative page on www.CMS.gov. We will evaluate the feasibility of the request to share additional information.

Comment: Several commenters supported a minimum sample size of 20 patients. However, the majority of commenters find a patient threshold of 20 to be too low to be statistically valid, which may result in inaccurate quality scores based on one outlier, and some commenters recommended increasing the threshold to 30 patients. Commenters recommended CMS use a higher threshold to ensure validity. Several commenters also urged CMS to provide an opportunity for the public to review reliability and validity tests.

Response: We appreciate the commenters' feedback regarding the 20 patient minimum sample size; however, it is important to note that all measures considered for public reporting are subject to additional validity and reliability tests prior to being publicly reported even if the minimum sample threshold is met. Therefore, we believe this threshold of 20 patients is

sufficient. In addition, it is a large enough sample to protect patient privacy for reporting on the website, and it is the threshold previously finalized for both the physician value-based payment modifier (VM) for most measures and the PQRS criteria for reporting measure groups (77 FR 69166). As mentioned, we will evaluate the feasibility of sharing additional information about the testing done. 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.⁵

Comment: Some commenters expressed concern with the comparability of measures reported through different reporting mechanisms and support an indicator specifying the differences.

Response: Though we understand concerns regarding including measures collected via different mechanisms, analyses are conducted to ensure that the consistencies and inconsistencies across reporting mechanisms are understood. Only those measures that are proven to be comparable and most suitable for public reporting will be included on Physician Compare and made publicly available. Comparability is one of the public reporting standards established for Physician Compare that must be met. Therefore, we will continue to report data from the available reporting mechanisms and make public a notation of which reporting mechanism was used.

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 will 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

⁵ 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.

stakeholder feedback, will determine specifically which measures are published on website 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 the data are collected, it is possible that clinical guidelines may have changed 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.

Comment: Commenters encouraged continued involvement of measure developers and stakeholders in the public reporting development process. Several commenters appreciated the continued collaboration with specialty societies via town hall meetings and other mechanisms. Several commenters advocated for more transparency by providing the opportunity for the public to comment on the deliberations of the Physician Compare TEP, regular engagement with interested stakeholders, and increased communication about the measure consideration process including methods and consumer interpretation of performance. Some commenters appreciated that CMS will continue to reach out to stakeholders in the professional community to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.

Response: As noted, section 10331(d) of the Affordable Care Act requires that the Secretary take into consideration input provided by multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, as added by section 3014 of the Act, in selecting quality measures for use on Physician Compare. We are also dedicated to providing opportunities for stakeholders to provide input. We will continue to identify the best ways to accomplish this so that all stakeholders have a voice and we are able to meet the statutory and

regulatory mandates and deadlines. We will review all recommendations provided for future consideration, and we strongly encourage all stakeholders to regularly visit the Physician Compare Initiative (<https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/>) page for information about the latest opportunities to engage with the Physician Compare team. Stakeholders are also encouraged to reach out with any questions and comments at any time via e-mail at PhysicianCompare@Westat.com.

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.

Comment: Most commenters supported consumer testing to ensure only meaningful measures are included on the website. One commenter urged CMS to consult a broader array of stakeholders during concept testing, including individuals with disabilities. Some commenters requested that CMS share with professional associations or measure developers any information obtained through consumer concept testing. A few commenters asked for more details on concept testing plans, while another recommended CMS use concept testing to evaluate the information currently on the Physician Compare site. One commenter would like CMS to assess the extent to which Physician Compare is effectively fulfilling the website's goals.

Response: We will continue to conduct consumer testing in terms of both usability testing -- to ensure the site is easy to navigate and functioning appropriately -- and concept testing -- to ensure users understand the information included on the website and that information

included resonates with health care consumers and allows the website to accomplish the goals as stated. We are continually working to test the information planned for public reporting with consumers and we regularly test the information currently on the website with site users. Once a set of measures is finalized as available for public reporting, we begin planning concept testing of the measures. Therefore, the measures finalized in this rule will be tested prior to publicly reporting in late 2017. We also continually work to ensure that valid, reliable, and meaningful information is included on the website. We will also continue to work to ensure that all stakeholders, including consumers and health care professionals, are included in the testing and review process as appropriate and feasible. We will review recommendations shared regarding sharing testing results for future consideration. It is important to note that many stakeholders are already involved in the dissemination of testing findings, and we are continually working to ensure the best audience for that information.

Comment: We received several comments that supported including all valid and reliable measures in the downloadable database while including only a select group of measures on the website. Some commenters urged CMS not to include data in a downloadable raw data file if it has already been deemed unsuitable for profile pages. There was concern that these data may be misused or misinterpreted by consumers, researchers, and the public.

Response: We will continue to include all measures that meet all stated public reporting standards that include that all measures included on Physician Compare must be statistically valid, accurate, reliable, and comparable in the downloadable file in order to further transparency. However, we will continue to limit the measures available on Physician Compare profile pages to those measures that meet these public reporting standards and are also of the greatest value to consumers. As noted above, consumer testing helps determine which information resonates with health care consumers. This will ensure that the measures presented on Physician Compare help consumers make informed health care decisions without

overwhelming them with too much information. However, it is very possible that there are strong measures that provide valuable clinical information that may be difficult for consumers to understand. We believe these are the types of measures that are more appropriately accessed in the downloadable database, rather than the profile pages. Again, only those measures that meet the public reporting standards established for Physician Compare will be included in either the downloadable database or the profile pages.

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. Although the 30-day preview has been previously finalized and we were not seeking comment on this, several comments were received. The following is a summary of the comments received on the 30-day preview period.

Comment: We received several comments in support of the 30-day preview period prior to publicly reporting quality data. Many commenters urged CMS to allow physicians and group practices the opportunity to correct and/or appeal any errors found in the performance information before it is posted on the site. Other commenters stated that a 30-day preview period was insufficient and requested that CMS extend the period to 45, 60, or 90 days. Several commenters stated the preview period should match the Informal Review timeline of 60 days. One commenter requested that if there is a pending PQRS Informal Review request, then public reporting should be delayed until there is a final resolution. Several commenters recommended that if an EP or group practice files an appeal and flags their demographic data or quality information as problematic, CMS should postpone posting their information until the issues are resolved. Some commenters sought clarification on how CMS plans to notify EPs of the preview

period and requested more detail about the process in the event an error is found during the preview period.

Response: As noted in this rule, the details of the 30-day preview period are communicated each year via various mechanisms, such as listserv announcements, Webinars, and other education and outreach opportunities, and information is always available on the Physician Compare Initiative page (<https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/>). There is currently no appeals process for data made public on Physician Compare. If a group practice or individual EP has any concerns regarding the data viewed during preview, they are provided with multiple options to reach out to the Physician Compare support team to report their concern and have the issue investigated. Any issue raised would be addressed prior to publicly reporting of the data. In addition, the PQRS and VM programs offer an annual Informal Review Period following the release of the Quality and Resource Use Reports (QRURs). We are currently working with the PQRS and VM programs to ensure that if there are data concerns raised during the Informal Review period, those concerns are taken into consideration around public reporting. Regarding concerns around demographic data, these data are driven primarily by the Provider Enrollment Chain and Ownership System (PECOS). There is detailed information available on the Physician Compare Initiative page about how to address any concerns with the demographic data available on Physician Compare. We strongly encourage all individual EPs and group practices to regularly review their data on Physician Compare and ensure their PECOS records are up to date. If there are any concerns, please contact the Physician Compare support team at PhysicianCompare@Westat.com.

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 website 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 website 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 website at <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 are made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare. The quality reports 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. In the CY 2014 PFS final rule with comment period, we finalized a decision that 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 were available for public reporting in CY 2015 (78 FR 74450). We also finalized a plan to make available for public reporting performance on certain measures that group practices reported 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. After review and analysis of these data, it was determined that neither 2014 EHR or registry data would be publicly reported in CY 2015. The 2014 EHR data will not be publicly reported on Physician Compare because CMS was unable to determine the accuracy of these data, and 2014 registry data will not be publicly reported because these data do not meet the public reporting standards. However, we will continue to analyze EHR and registry data for future inclusion on the website in 2016 and beyond.

We received comments specifically about EHR measures.

Comment: Commenters were opposed to publicly reporting EHR measures citing the CY 2014 data inaccuracies, specifically given the number of errors in the eCQM submission data. Some commenters stated it was too soon to publicly report data from eCQMs without additional work to verify the validity and accuracy of the measure results. One commenter encouraged CMS to develop information to help the public to better understand these data.

Response: We decided not to publicly report 2014 EHR data because we were unable to determine the accuracy of these data. Only comparable, valid, reliable, and accurate data will be included on Physician Compare. In addition, all measures slated for public reporting will be consumer tested to ensure they are accurately understood prior to public reporting. If concerns surface from this testing, we will evaluate the best course forward to ensure only those measures

that meet the public reporting standards established for Physician Compare are included on the site.

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).

In late CY 2015, certain 2014 individual PQRS measure data reported by individual EPs are also available for public reporting. Specifically, we finalized to make 20 individual measures collected through a registry, EHR, or claims available for public reporting (78 FR 74453 through 74454). These are measures that are in line with those measures reported by groups via the Web Interface. As noted above, however, both the 2014 EHR and registry data are not being publicly reported for either group practices or individual EPs who reported these data.

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 were finalized as available for public reporting in CY 2015 (78 FR 74454). Again, these data are ultimately not going to be publicly reported in late 2015 because they are collected only via registry.

We continue to expand public reporting on Physician Compare by making an even broader set of quality measures available for public reporting on the website 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 finalized to make twelve 2015 CAHPS for PQRS summary survey measures available for public reporting 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 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 finalized to make all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims available for public reporting in CY 2016 on Physician Compare (79 FR 67773).

Furthermore, in support of the HHS-wide Million Hearts initiative, four 2015 PQRS measures reported by individual EPs in support of Million Hearts will be available for public reporting in CY 2016.

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 that 2015 Qualified Clinical Data Registry (QCDR) PQRS and non-PQRS measure data collected at the individual EP level are available for public reporting in late CY 2016. The QCDR is required to declare during their self-nomination if it plans to post data on its own website and allow Physician Compare to link to it or if it 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 25 for a summary of our previously finalized policies for public reporting data on Physician Compare.

TABLE 25: 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	14 measures reported via the WI for group practices of 2 or more EPs reporting under PQRS with a minimum sample size of 20 patients.
2014	Expected to be late 2015	WI, Survey Vendor	All Web Interface measures reported by Shared Savings Program ACOs, and CAHPS for ACO measures.
2014	Expected to be late 2015	WI, Certified Survey Vendor	8 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	Claims	A sub-set of 6 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through claims with a minimum sample size of 20 patients.
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

Data Collection Year	Public Reporting Year	Reporting Mechanism(s)	Quality Measures and Data for Public Reporting
			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	QCDR	All individual EP QCDR measures, including PQRS and non-PQRS measures.

3. Final 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 public reporting on the website. 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 proposed (80 FR 41811-41814) 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 website. We received several comments on the phased approach to public reporting. A summary of the comments received follows.

Comment: While many commenters supported continuing the phased approach to public reporting of quality data, several commenters noted concern with what they perceive is an aggressive timeline for publicly reporting physician performance data. Commenters supported a more gradual approach to public reporting to allow time to evaluate the public response to data prior to widespread implementation, ensure accuracy, and permit data to be presented in a format that is easy to understand, meaningful, and actionable for both patients and physicians. Some

commenters opposed the extensive expansion until existing website problems are addressed. Several commenters suggested focusing on educating and implementing the Merit-based Incentive Payment System (MIPS) program before expanding public reporting.

Response: We believe that public reporting of quality data has been a measured, phased approach which started with publicly reporting just five 2012 PQRS GPRO measures collected via the Web Interface for 66 group practices and 141 ACOs (76 FR 73417) and continued with a similarly limited set of 2013 PQRS GPRO Web Interface measures (77 FR 69166). We started to build on this plan with the CY 2014 PFS final rule with comment period (78 FR 74446). In that rulemaking, we adopted additional PQRS measures available for public reporting, including a subset of individual EP PQRS measures. Therefore, the proposals put forth this year are just the next step in the process to realize the goals of Physician Compare. We are confident that taking this phased approach has afforded us the opportunity to prepare for this significant expansion.

Throughout this process, we have been engaging with consumers and stakeholders and regularly testing the site and the information to be included to ensure it is accurately presented and understood. We are also continually working to improve the website and the administrative and demographic information included. We continue to encourage physicians, other health care professionals, and group practices to ensure their information is updated in PECOS so that we can ensure the most accurate information is available on Physician Compare. We also encourage individuals and groups to reach out to the Physician Compare support team at PhysicianCompare@Westat.com for any questions or concerns regarding the information included on the website.

We are committed to public reporting to provide consumers with information to help them make informed health care decisions. Even though we will be moving to MIPS as required by the Medicare Access and CHIP Reauthorization Act (MACRA), we are committed to

continue providing this useful information to consumers and to continue to be transparent so that health care professionals can evaluate their own performance and the performance of their peers. As we move towards implementation of the new MIPS program, we will continue to engage and educate our stakeholders.

a. Value Modifier

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).⁶ We proposed (80 FR 41811) 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 physician value-based payment modifier (VM). This VM indicator can help consumers identify higher quality care provided at a lower cost. 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. 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-friendly, easy-to-understand format. We proposed 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. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include a green check mark indicator of the names of those individual EPs and group practices who receive the VM upward adjustment on profile pages on Physician Compare.

⁶ <http://www.hhs.gov/strategic-plan/goal1.html>.

Comment: We received both positive and negative comments on this proposal.

Supporters noted that the addition of VM data supports transparency, encourages improvement, and provides important information to the public. One commenter suggested adding additional VM performance information to the website. Several commenters urged CMS to include educational information about the VM for consumers or an explanation for physicians who are not eligible for the VM. Another commenter urged CMS to clarify which performance year data will be published on Physician Compare to ensure the information is accurately understood. One commenter suggested collaborating with consumer advocacy groups to educate consumers about VM data if the visual indicator is included.

However, several commenters had significant concerns that the VM is not well-understood by the public, may be misinterpreted, or does not provide value to consumers. Many commenters were also opposed to this proposal due to concerns with the VM calculation methodology and the resulting proportion of health care professionals that will receive "average" scores for the cost and/or quality composite. One commenter recommended that EPs who participate in programs that exempt them from VM should receive a checkmark because without this indicator, they would appear lower quality. Several commenters opposed these data being added on the profile page, but supported inclusion in a downloadable database. Some commenters also noted that the VM program will sunset after 2018, and suggested waiting to publicly report cost data until the MIPS is implemented. One commenter suggested an indicator for participating in a QCDR is a better indicator of physician quality and overall value than the VM.

Response: We appreciate the commenters' feedback, and we appreciate the concerns raised. We do believe that in time, information such as this can provide consumers with valuable information to help them make informed health care decisions and help CMS advance our overall quality strategy. We agree that this or similar information needs to be presented on

profile pages in a way that will ensure it is accurately understood and interpreted and is seen as valuable information from the consumer perspective. We also appreciate that because the VM adjustment will end after CY 2018, it may be confusing to consumers to add a new indicator for only a short period of time followed by potentially another indicator related to the MIPS in later years. As a result, we are not finalizing this proposal, and therefore, will not be including a visual indicator of the VM upward adjustment on profile pages at this time. Regarding the recommendation to add an indicator for participation in a QCDR, that is not something currently being considered as we appreciate this is not a concept consumers are familiar with. However, we will take it into consideration for potential future evaluation.

b. Million Hearts

In support of the HHS-wide Million Hearts initiative, we included 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 proposed (80 FR 41811) 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 that was proposed (and is being finalized in this final rule) under PQRS. 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 solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include an indicator on profile pages for EPs who satisfactorily report the Cardiovascular Prevention measures group in support of Million Hearts.

Comment: Commenters supported including an indicator on profile pages for individual EPs who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of Million Hearts. One commenter suggested adding context and information about the program to help consumers better understand the information. One commenter recommended that the final rule reference the Million Hearts measures by the PQRS number rather than the short name. Another commenter suggested recognizing EPs that report other cardiovascular PQRS measures in addition to those who report the specific measure group.

Response: We are committed to supporting the Million Hearts initiative and we believe that recognizing EPs who report this measures group is aligned with promoting the Million Hearts initiative. We appreciate that some commenters would like additional measures to be considered in support of the initiative, and we will review this suggestion for potential future rulemaking. We are also working on a website update that will provide more plain language descriptions and context of all quality programs represented on the site to ensure consumers have the context and understanding commenters noted is important. We are also consumer testing this information on an ongoing basis to ensure consumers are getting the most out of this information. As a result, we are finalizing this proposal to include a visual indicator on EP profile pages in support of the Million Hearts initiative as it is deemed valuable by consumers and including this information may incentivize health care professionals to focus on the Million Hearts measures.

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 policy to make available for public reporting on

Physician Compare all PQRS GPRO measures collected in 2015 via the Web Interface, registry, or EHR. In the proposed rule, we proposed (80 FR 41811) 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 would be represented on the website. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to make PQRS GPRO measures across all reporting mechanisms for groups of 2 or more EPs and Shared Savings Program ACO measures available for public reporting.

Comment: We received both positive and negative comments regarding our group practice proposal. Commenters in support noted that publicly reporting quality measures is helpful to consumers and supports transparency. In general, commenters were more supportive of publicly reporting group level measures over individual EP level measures. Some commenters, however, opposed the continued public reporting of PQRS data generally, noting concerns such as the accuracy of current data reported via an EHR, the potential for consumer misinterpretation, and the limited measures available for some specialists to report. One commenter suggested CMS focus on preparing for MIPS rather than continuing with the current public reporting plan.

Response: We are committed to public reporting to provide consumers with information to help them make informed health care decisions. We are also working to fulfill the public reporting requirements of the Affordable Care Act. Even though we will be moving to MIPS as a result of the MACRA, we are committed to continuing our phased approach to public reporting

and providing this useful information to consumers consistently year to year, as possible. We are also committed to supporting transparency so that health care professionals can evaluate their own performance and the performance of their peers. We understand that there are concerns with the available data. As noted above, all data must meet the public reporting standards outlined in this rule and in previous rulemaking in order to be publicly reported. For instance, because the accuracy of the 2014 data reported via an EHR could not be determined, these data will not be publicly reported. Data that do prove to be valid, reliable, accurate, comparable, and that resonate with consumers, however, will be publicly reported.

Regarding concerns about potential consumer misinterpretation of the data, we do conduct regular consumer testing to address this issue. In general, consumers find this information interesting and beneficial in their decision making process. If a measure is not accurately interpreted or well understood, or if consumers do not find it to be valuable, that measure is not considered for public reporting on Physician Compare profile pages. We do appreciate that PQRS does not contain a similar number of measures for all possible specialties; we are working on strategies to help fill this gap. One strategy is looking toward QCDRs, which are better able to address the needs of specific specialties with relevant measures.

After considering the issues raised by commenters and for the reasons we articulated, we are finalizing our proposal to continue to make all PQRS group practice level and ACO Shared Savings Program measures available for public reporting annually, including making the 2016 PQRS group practice and ACO data available for public reporting on Physician Compare in late 2017.

d. Individual EP PQRS Reporting

Consumer testing indicates that consumers are looking for measures regarding individual doctors and other health care professionals above all other data. As a result, we decided to make individual EP level measure data available for public reporting on Physician Compare starting

with a subset of 2014 PQRS measures (78 FR 74451). We expanded this plan by making all 2015 individual EP level PQRS measures collected through a registry, EHR, or claims available for public reporting (79 FR 67773). Through 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 proposed 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 would be included on Physician Compare in 2017). For individual EP measures, the measure performance rate would be represented on the website. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to make all individual EP level PQRS measures available for public reporting on Physician Compare.

Comment: As with the group practice level PQRS measures, we received both positive and negative comments regarding this proposal. Commenters in support again noted that quality measures are helpful to consumers and support transparency. Several commenters that supported publicly reporting group level measures did not support reporting individual EP level measures noting that individual level reporting may be subject to more data accuracy issues and suffer from small sample sizes. Another commenter asked for clarification about which performance score is publicly reported if an EP reports PQRS data through multiple reporting mechanisms.

Response: We appreciate the commenters' feedback on individual EP PQRS measures. Again, as is the case with all measures under consideration for inclusion on Physician Compare, the public reporting standards established for Physician Compare must be met for the measure to be publicly reported. As a result, if analyses show that the data are not accurate, valid, reliable, comparable, or do not resonate with consumers, they will not be publicly reported on Physician Compare profile pages. Regarding concerns around small sample sizes, only those measures that

are reported for the accepted sample size of 20 patients and that meet all stated public reporting standards will be publicly reported. We understand that it may be harder to meet this minimum sample size at the individual EP level. However, that will simply mean the measure is not listed on the individual EP's profile page and no performance rate is reported. PQRS does encourage EPs to report via a single reporting mechanism. If data from multiple reporting mechanisms are deemed eligible for public reporting and an individual EP reports through more than one of the available mechanisms, we will look at the reporting mechanism that is used to determine PQRS satisfactory reporting and work to use the performance rate consistent with that mechanism.

As a result of the comments received and the importance of individual EP level quality measure data to consumers, we are finalizing our proposal to continue to make all PQRS individual EP level PQRS measures available for public reporting annually, including making the 2016 PQRS individual EP level data available for public reporting on Physician Compare in late 2017.

e. Individual EP and Group Practice QCDR Measure Reporting

As previously stated, 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 when deciding who they should 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 proposed 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 (80 FR 41812). In addition, we proposed 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 (80 FR 41812). Previously, the PQRS program only included QCDR data at the individual EP level. In section III.I.2.a. of this final rule with comment period, we are finalizing, under the PQRS, a decision to expand QCDR reporting 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 proposed 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 would be represented on the website. We solicited comments on these proposals.

The following is a summary of the comments we received on our proposal to make both group practice and individual EP level QCDR data available for public reporting on Physician Compare.

Comment: Many commenters support publicly reporting QCDR measures for group practices, as well as individual EPs, noting that it promotes flexibility in reporting, provides additional information to consumers, and addresses sample size concerns. One commenter requested that CMS explore ways for quality reporting to be publicly available at the level of the entire care team. Another commenter expressed concern that attributing group practice data to an individual physician does not provide the necessary information to allow the consumer to determine how the individual EP performed on those measures.

There were also some general concerns about QCDR data including concerns that QCDR data are too new, not comparable to PQRS measures, not accurate and reliable, and potentially confusing to consumers. One commenter suggested holding public reporting of QCDR data until more specialties are able to report via QCDRs.

Response: We appreciate the commenters' feedback on these QCDR proposals. We agree that making QCDR data, both PQRS and non-PQRS measures, available for public reporting helps fill potential gaps left by the currently available PQRS data. We also believe these measures add great value for consumers as they provide a greater diversity of quality information at both the group practice and individual EP levels, and thus, further help consumers make informed decisions about their health care. At this time, it is only possible for CMS to consider measures attributed to either the group practice level or the individual EP level. Other attribution options are not possible at this time, but will be taken under consideration for the future.

It is important to note that data collected at the individual EP level, whether through a QCDR or through other PQRS reporting mechanism will only be publicly reported at the individual EP level, and data collected at the group practice level will only be reported at the group practice level. Group practice data will never be publicly reported on an individual EP profile page because it would not be accurate to attribute the group's performance rates to only one EP.

Regarding the general concerns raised about publicly reporting QCDR data, it is important to emphasize that data submitted by QCDRs must meet the same public reporting standards as all other data submitted to CMS. If a QCDR submits a PQRS measure and that measure data is not deemed comparable to data submitted via other PQRS reporting mechanisms, the data will not be publicly reported because all data publicly reported must be comparable to ensure one measure is evaluating each EP or group in the same way regardless of how the data were collected and submitted to CMS.

It is expected that non-PQRS measures submitted via QCDRs are likely to be unique from the available PQRS data. This is considered one of the greatest benefits of the QCDR data. These measures are likely to be more specific to specialties otherwise less represented in PQRS

and to be a strong fit for those reporting them. Considering the measures are relevant to the group or EP they are representing, we believe this provides a benefit to consumers reviewing the data. We appreciate that not all groups or EPs may have the opportunity to participate in a QCDR, but we see significant value in making the data that are now accessible available for public reporting for these reasons. Again, as with all data under consideration for public reporting, consumer testing will be done to ensure measures included on Physician Compare are accurately interpreted and deemed valuable by consumers.

Understanding the value of these data, the opportunity for these data to fill gaps currently in the PQRS program, and the relevancy of these data to many specialties, we are finalizing this proposal to make group practice and individual EP level QCDR data, both PQRS and non-PQRS measures, available for public reporting on Physician Compare annually, including making 2016 data available for public reporting in late 2017.

Each QCDR will be required to declare during its self-nomination if it plans to post data on its own website and allow Physician Compare to link to it or if the QDCR plans to 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 will 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 TEP, we proposed (80 FR 41812-41813) to publicly report on Physician Compare an item, or measure-level, benchmark derived using the Achievable Benchmark of Care (ABC™)⁷ 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. We proposed 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).

As explained, 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

⁷ 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.

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 proposed to 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 would produce 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 who were treated by the top doctors, producing the ABCTM benchmark.

To account for low denominators, ABCTM 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 proposed (80 FR 41813) to use the ABC™ methodology to generate a benchmark which could 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.^{8,9,10}

To summarize, we proposed 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 solicited comments on this proposal.

⁸ 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.

⁹ 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.

¹⁰ 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.

The following is a summary of the comments we received on our proposal 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.

Comment: Many commenters supported the use of benchmarks to help consumers make informed health care decisions and specifically the proposed ABC™ methodology, noting this is a valuable and useful tool for consumers and a valid and reliable way to approach a benchmark and star ratings. However, some commenters stated it was too soon to publicly report a benchmark and suggested phasing in or testing and sharing the benchmark privately with EPs and group practices for internal improvement first prior to making the benchmark publicly available. Some commenters asked for up to 2 years of internal use prior to public reporting. Other commenters would like CMS to wait to apply a benchmark until MIPS is implemented in order to understand how the methodology would be applied in the context of MIPS.

Some commenters noted concern that measures are currently not risk-adjusted and that the proposed methodology may not be appropriate for all measures. Multiple commenters, both those who support and do not support the specific proposal, noted concerns about the need to stratify any benchmark developed by specialty, stratify by reporting mechanism, and risk-adjust the benchmark. Some commenters urged CMS to educate physicians and consumers on the benchmark methodology. Several commenters appreciated the stakeholder engagement conducted by the Physician Compare team regarding the benchmark methodology selection and encouraged continued engagement in the future.

Several commenters also asked for clarification on how the pared-mean was determined and how this method can be applied to both process measures and outcome measures. Some commenters suggested increasing the pared-mean to 25 percent and commenters suggested other benchmark methodologies, including an approach that recognizes self-improvement over time

and peer-to-peer performance. One commenter asked for the opportunity to review the database and provide a clear demonstration of the benchmark's validity. Additional commenters noted that benchmarks using the ABC™ methodology is too complex and will be difficult for consumers to understand, and encouraged consumer testing to remedy this potential problem. Several commenters urged CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. Several commenters urged CMS to allow QCDRs to determine their own benchmark approach.

Response: We are particularly appreciative of the collaborative effort of the many stakeholders who took the initiative to participate in the stakeholder outreach process conducted to determine a suitable benchmark methodology to propose for public reporting on Physician Compare. We look forward to continuing this collaborative approach. We also appreciate the concerns raised. Although we see the reasons why some commenters would first like the benchmark to be viewed privately, we reiterate the significant value in adding a benchmark to Physician Compare now. Consumers need tools to best understand the data and to make accurate and appropriate comparisons. A benchmark such as this can provide this valuable tool. We are committed to continually working to make the information on Physician Compare as easy to understand and consumer friendly as possible, and adding a benchmark is a critical next step in this process.

Regarding the commenters' concerns about risk adjustment, we agree that risk adjustment will become increasingly important as we move to more outcome measures, specifically at the individual EP level. We actively encourage measure developers to produce measures that are risk adjusted. We believe that it is most appropriate to approach risk adjustment at the measure development level versus trying to adjust after the fact at the benchmarking stage, especially when data are submitted via reporting mechanisms that do not provide the necessary information to risk adjust after data collection is complete. We will continue to conduct analyses to ensure

all data, including the benchmarks, meet the stated public reporting criteria, and therefore, are showing variation in performance and not in other factors, such as region or population of care.

Regarding stratifying the benchmark, one consideration is the negative effect of over-stratification. At this stage in public reporting, looking to stratify by too many criteria can lead to data groupings so small that there can be no meaningful or statistically relevant comparisons made. Also, it is important to remember that searches on Physician Compare are conducted by location and specialty. In this way, when a consumer is evaluating data on the Physician Compare website, they are generally looking at health care professionals in the same location practicing in similar or the same specialties. Understanding the limitations to stratifying at this time, there is one stratification consideration that we believe is not only valuable but necessary as we work to ensure data included on the website are comparable.

We are in favor of stratifying by reporting mechanism at this time, which would mean creating a benchmark by measure by reporting mechanism. This would help remove the complexity and potential differences between the same measure collected via multiple reporting mechanisms and help solve some of the concerns raised about the available PQRS data. It would also remove the burden of interpretation across mechanisms from consumers. It is important to note that this benchmark proposal does only apply to PQRS data. QCDRs are free to develop their own benchmark methodology and submit their methodology and benchmark rates to Physician Compare for public reporting consideration for non-PQRS measures when and where appropriate.

One of the benefits of the ABC™ methodology is that it has been tested in a number of scenarios and the pared-mean has been found to be statistically reliable, valid, and accurate when producing a truly achievable benchmark that can be used to measure and improve quality performance. We appreciate the recommendation to look at a pared-mean that includes more than the top 10 percent of patients served by the top performers. However, we believe that

increasing this percentage is likely to dilute the benchmark and overstate quality performance on a given measure. That said, we are conducting ongoing testing evaluating this methodology as applied to the available PQRS data, and we will actively reach out to stakeholders to share information about the results of this statistical analysis, as well as ongoing consumer testing, to ensure stakeholders are aware of the specific application of the benchmark and the reliability, validity, and accuracy of the benchmark for the available PQRS process and outcome measures. We will use the most current data to ensure the benchmark is the best measure of timely quality care. Therefore, additional specifics about the application of the benchmark in terms of the specific star attribution, including but not limited to statistical analysis of the 2016 data, star display, and consumer testing, will depend on data that have not been collected yet. We will provide this information as it is available but in advance of publicly reporting the benchmark. It is important to note that initial consumer testing indicated an ABC™ derived benchmark could be well received and understood by consumers on Physician Compare.

We do appreciate the comments that requested that CMS evaluate using a consistent benchmark methodology across programs. We are continually evaluating ways to align where and as possible, and will take this recommendation into consideration for the future. One benefit of the ABC™ methodology is that it is potentially applicable across care settings and measure types.

After considering the comments and stakeholder and expert feedback, as well as testing conducted to date, and for the reasons we noted, we are finalizing our proposal to publicly report on Physician Compare an item, or measure-level, benchmark derived using the ABC™ methodology annually based on the PQRS performance rates most recently available stratified by reporting mechanism for both group practice and individual EP level measures.

In addition to receiving comments about using the ABC™ methodology to derive the benchmark, we also received comments on our proposal to use the ABC™ derived benchmark to

systematically assign stars for the Physician Compare 5 star rating. The following is a summary of these comments.

Comment: Several commenters supported the systematic assigning of a star rating based on the proposed benchmark methodology. Other commenters opposed star ratings, generally, noting that they are concerned such ratings oversimplify performance data. These commenters also raised concerns that disparate quality scores could result in inappropriate distinctions of quality for physicians whose performance scores are not statistically different. Several commenters asked for additional details on how the stars will be assigned and urged CMS to provide clear explanations to the public about how to interpret the star ratings.

Response: We are committed to moving to a star rating system on Physician Compare as this is a consumer friendly way to share such complex information as the quality measure data being made available. As with all information available for public reporting on Physician Compare, the benchmark information and the resulting star ratings need to meet the public reporting standards of statistically valid, accurate, reliable, and comparable data. The goal of using a benchmark such as one derived from the ABC™ methodology is to have a star rating system that distinguishes statistically significant quality differences. Using this methodology can help us ensure that five star performance is statistically different than four star performance, etc. As noted in this section, additional details based on ongoing analysis with the most recently available data will be shared with stakeholders. In addition, information about how stars will be specifically assigned using the ABC™ methodology, star display, and plain language will be shared when the relevant data are available. Finally, we will continue to work to ensure that the star rating system used is accurately understood and interpreted by consumers. Consumer testing is therefore ongoing.

Understanding the value of a star rating system for consumers, we are finalizing our proposal to use the ABC™ derived benchmark to systematically assign stars for the Physician

Compare 5 star rating.

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, 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 proposed (80 FR 41813) 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 CAHPS for PQRS reported data will be included on the website in 2017). The patient experience data available that we proposed to make available for public reporting are the CAHPS for PQRS measures, which include the CG-CAHPS core measures. For group practices, we proposed to annually make available for public reporting a representation of the top box performance rate¹¹ 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.

¹¹ 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.

- 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 solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to publicly report CAHPS for PQRS data for group practices of 2 or more EPs that meet all stated public reporting criteria.

Comment: Many commenters supported expanding public reporting of CAHPS for PQRS measures, noting that patient experience data is highly relevant to consumers.

Commenters stated that other patients' assessments of their experience with a given group practice or health care professional are no doubt helpful in the health care decision making process. Some commenters supported including a benchmark for the CAHPS summary measures. Several commenters also urge CMS to collect and report individual EP level patient experience data. Some commenters opposed the proposal, citing concerns around consumer interpretation of patient reported data and that these data may not capture patient experience related to all specialties, such as hospitalists, other hospital-based professionals, and surgical practices. One commenter had concerns with the "Stewardship of Patient Resources" measure because the measure does not address the numerous barriers to patients accessing to care. Several commenters supported adding other types of patient experience data to Physician Compare, including Surgical CAHPS® and experience data collected via other sources. Another commenter suggested reporting patient experience data for primary care physicians and only

clinical quality performance for specialists.

Response: We agree that these patient experience data are very valuable to consumers, and as noted, consumer testing has consistently shown that these measures aid decision making and are wanted by consumers. Consumer testing has also shown that these measures are generally well understood and accurately interpreted by consumers. CAHPS measures are extensively tested and proven to be statistically valid. We are confident these measures are an appropriate and statistically relevant indicator of patient satisfaction.

We do appreciate the comments regarding other types of patient experience data, as well as the inclusion of a CAHPS benchmark, and will consider these recommendations for the future. We do understand that not all measures under consideration for public reporting equally apply to all types of professionals included on Physician Compare. However, we do believe that the CAHPS for PQRS measures apply to the large majority of professionals currently represented on the site. We also appreciate the request for CAHPS for PQRS measures at the individual EP level. This is something consumers have also requested in testing. Unfortunately, at this time, CAHPS for PQRS measures are only available and tested at the group practice level.

Again, as with all measures available for inclusion on Physician Compare, the measures must meet the stated public reporting standards. Any concerns about specific measures are reviewed against these criteria prior to consideration for public reporting.

After considering the comments received and given that CAHPS for PQRS data are highly valued by consumers, we are finalizing our proposal to make all twelve summary survey CAHPS for PQRS measures available for public reporting on Physician Compare annually for groups of 2 or more EPs reporting via a CMS certified CAHPS vendor.

h. Downloadable Database

(a) Addition of VM Information

To further aid in transparency, we also proposed (80 FR 41813-41814) to add new data

elements to the Physician Compare downloadable database at <https://data.medicare.gov/data/physician-compare>. Currently, the downloadable database includes all quality information publicly reported on Physician Compare, including quality program participation. In addition, the downloadable database includes all measures submitted and reviewed and found to be statistically valid and reliable. We proposed (80 FR 41813) 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 proposed (80 FR 41813) 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 analysts, and researchers who are familiar with 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 can be packaged and explained in such a way that it is accurately interpreted, understood, and useful to average consumers. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include this additional VM data to the Physician Compare downloadable database.

Comment: Several commenters expressed significant concerns about adding this VM data to the Physician Compare downloadable database for group practices and individual EPs because the VM is not well-understood by the public, and is perceived as not providing value to the consumer or accurately portraying quality and cost. One commenter noted that consumers can still access this data in the downloadable database. Several commenters were concerned that

this data could be misused by researchers or media. One commenter suggested that VM information should be shared with specialty societies rather than publicly reported. Many commenters were also opposed to this proposal due to concerns with the VM calculation methodology and the portion of group practices and health care professionals that will receive "average" scores for the cost and/or quality composite. One commenter urged CMS to put in place a 30-day period for EPs and group practices to review any VM information that will be added to the downloadable database. Conversely, several commenters supported adding VM information to the downloadable database, noting that it promotes transparency and provides useful data to the public. Some commenters also noted that these data support research and generate further learnings about the VM methodology.

Response: We do understand the concerns raised about making VM data publicly available. Our experience shows that average consumers are not the primary audience for the downloadable database. In fact, testing has shown that most average consumers do not want or believe they know what to do with that level of detailed data. Therefore, we are not concerned that adding these data to the downloadable database will disadvantage consumers. We do appreciate that these or any data provided in the downloadable database could be misused. However, we do believe that the benefits of transparency and potential learnings for health care professionals, specialty societies, researchers, and other stakeholders, as noted by some commenters, outweigh these concerns. As noted by commenters, making these data available to the informed public could lead to improvements in the methodology and greater understanding of cost and quality. Regarding the request for these data to be made available for preview, we do not currently provide a preview period for the downloadable database, but the cost and quality scores included will match those provided in existing feedback reports. These reports are generally made available for private review more than 30 days prior to publicly reporting the data on Physician Compare.

As a result of our commitment to increased transparency and the other reasons we noted, and after considering the public comments, we are finalizing this proposal to add cost and quality tier, as well as adjustment, information to the Physician Compare downloadable database for the 2018 VM based on 2016 quality and cost data.

(b) Addition of Utilization Data

In addition, we proposed (80 FR 4183-4184) 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 Health care Common Procedure Coding System (HCPCS) code. Under section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114-10, enacted April 16, 2015), beginning with 2016, the Secretary shall integrate utilization data information on Physician Compare. This 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 proposed that the data be added to the downloadable database versus the consumer-focused website 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 website. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include utilization data in the Physician Compare downloadable database.

Comment: Some commenters supported the addition of utilization data to the public downloadable database, noting that these data support transparency and may be useful to researchers for analysis. They do however note that these data are not intended for the average Medicare consumer. Several commenters expressed concern with the accuracy of these data and the potential for misinterpretation or misuse of the data. Some commenters request that these data include disclaimers about the limitations of utilization data and request that physicians be allowed to submit corrections where the data are inaccurate or outdated. Several commenters also felt that utilization data are not only not intended for consumer use but do not align with Physician Compare's goals. Some commenters noted that utilization data are already available on a different CMS website. One commenter suggested developing a profile based on patient characteristics from the data. Another commenter requests safeguards or summary conclusions from the claims data that would be meaningful for consumers. One commenter urged CMS to limit the release of these data to professional societies and work to determine the most appropriate use.

Response: We agree that these data are not intended for or well understood by the average Medicare consumer. This has been illustrated in consumer testing to date. Again, it is important to note that consumers are not a primary audience for the downloadable data file. These data are potentially of great value to many stakeholders. The data are already public on another CMS website, as mentioned, but including them with the other Physician Compare data could help provide useful context that could better ensure more appropriate use of the data. As noted above, all data shared publicly could potentially be misused. But, again, we believe the benefits of transparency outweigh these concerns and we will work to determine the best method for displaying the data. We appreciate the recommendations for alternative ways to use or include these data on the consumer-facing site or ways additional context could be added to these data. We will review these recommendations for the future.

Given that section 104(e) of MACRA mandates integration of these data on Physician Compare and because we believe that adding these data to the downloadable database advances our transparency goals, we are finalizing our proposal to include utilization data in the Physician Compare downloadable database. Not all available data will be included. The specific HCPCS codes included will be determined based on analysis of the available data, focusing on the most used codes. Additional details about the specific HCPCS codes that will be included in the downloadable database will be provided to stakeholders.

(i) Board Certification

Finally, we proposed (80 FR 41813) adding additional Board Certification information to the Physician Compare website. 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 website. Such board certification information is of interest to consumers as it provides additional information to use to evaluate and distinguish between EPs on the website, 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 website and find quality data that can help them make informed decisions. Specifically, we proposed to add to the website 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 website and have demonstrated that they have the data to facilitate inclusion of this information on the website. These two boards also fill a gap, as the ABMS does not certify Optometrists and only certain types of DOs are covered by ABMS Osteopathic

certification. In general, we reviewed interest from boards as it was brought to our attention, and if the necessary data were available and appropriate arrangements and agreements could be made to share the needed information with Physician Compare, additional board information could be added to the website in future. At this time, however, we specifically proposed to include ABO and AOA Board Certification information on Physician Compare. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to adding additional Board Certification information to Physician Compare, specifically adding ABO and AOA Certification.

Comment: Commenters supported adding ABO and AOA Board Certification to Physician Compare. One commenter recommended that the name of the certifying board be included on the site so it is clear whether the certificate is issued by an ABMS Member Board or another board. Another commenter urged CMS to consider multiple certifications within a specialty and to develop a tool for Medicare beneficiaries and other health care consumers to view a comparison of the multiple certifications on the site. Several commenters requested the addition of other boards, including the American Board of Audiology (ABA), a Certificate of Clinical Competence in Audiology (CCC-A), American Board of Physician Specialties (ABPS), American Board of Physical Therapy Specialties (ABPTS), ASHA Certificate of Clinical Competence in Speech-Language Pathology (CCC-SLP), Board Certified Specialist in Child Language and Language Disorders, Board Certified Specialist in Fluency and Fluency Disorders, Board Certified Specialist in Swallowing and Swallowing Disorders, and Board Certified Specialist in Intraoperative Monitoring from ASHA. One commenter noted that there is no category for specialized certifications for professionals other than physicians on Physician Compare and requested the opportunity to provide input should such a category be under consideration. Another commenter requested that the site include information about hospitalists

who choose to pursue a Focused Practice in Hospital Medicine (FPHM) Maintenance of Certification (MOC).

Response: We particularly appreciate the many suggestions provided for additional Boards to consider for inclusion on the website and for additional suggestions regarding how to display this information on the website. We also appreciate the comment regarding the need to evaluate including information for EPs beyond physicians. All of these recommendations will be taken under consideration for the future to evaluate if they are feasible and/or considered a value added through consumer testing. For those Boards that have specifically requested being considered for inclusion on the website, we will work with each Board to assess if the Board has the data available and comparable information needed to include the Certification information on the website and consider whether such boards would be appropriate for consideration in future rulemaking.

As a result of the overall support for adding additional Board Certification information to Physician Compare and for the reasons we specified above, we are finalizing our proposal to add this specifically ABO and AOA Board Certification information.

Table 26 summarizes the Physician Compare measure and participation data proposals finalized in this final rule.

TABLE 26: Summary of Measure and Participation Data Finalized for Public Reporting

Data Collection Year*	Publication Year*	Data Type	Reporting Mechanism	Quality Measures and Data Finalized 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 under PQRS in support of Million Hearts.
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.

Data Collection Year*	Publication Year*	Data Type	Reporting Mechanism	Quality Measures and Data Finalized for Public Reporting
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: <ul style="list-style-type: none"> • 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 finalized to be reported annually. The table only provides the first year in which these data 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. Public Comment Solicited on Issues for Possible Future Rulemaking

a. Quality Measures

In addition to the proposals we made in the proposed rule, we solicited comment on several new data elements for possible inclusion on the individual EP and group profile pages of Physician Compare through future rulemaking. 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 stated that 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 sought comment on potential measures that would benefit future public reporting on Physician Compare. We are working to identify possible data sources and we sought 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.

The following is a summary of the comments we received on our request for comment on future quality measure needs.

Comment: We received comments on potential measures to report on Physician Compare in the future. Commenters supported including outcome measures, including clinical outcomes and patient-reported outcomes. One commenter noted that outcome measures must include a risk adjustment methodology. Other commenters supported patient safety, care coordination, cross-cutting, and patient and family experience of care measures. Commenters suggested specialty specific measures, including audiology, urology, and neurology measures. One commenter recommended the continued partnership with the professional associations, contractors, and CMS for future measure determination, and noted that measures used for Physician Compare should be included in the proposed rule for public comment. One commenter suggested measures for appropriate access to the health care professional/group practice offices, culturally and linguistically competent services including successful trainings attended, availability of appropriate transportation with equipment, geriatrics specialty/training, patient experience measures with qualitative data, and patient reported measures, including ones that capture patient activation. One commenter suggested a common set of EP level performance measures that would apply across all payment programs, and another urged CMS to incorporate the Core Quality Measures Collaborative's aligned measure sets. One commenter

opposed the future public reporting of performance information for any quality measures that are not reported under federally required quality reporting programs.

Response: We will review all comments and consider these suggestions for possible future rulemaking.

b. Medicare Advantage

We also sought comment on adding Medicare Advantage information to Physician Compare individual EP and group practice profile pages. Specifically, we sought 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 website. 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 could help ensure that consumers have access to all of the quality data available to make an informed health care decision.

The following is a summary of the comments we received on our request about possibly integrating Medicare Advantage information with Physician Compare information in the future.

Comment: Several commenters supported adding Medicare Advantage information to the Physician Compare individual EP and group practice profile pages, noting that it would further assist consumers with health care decision making and fill a current gap in the available data. One commenter noted that certain services are provided outside of the scope of benefits under traditional FFS Medicare, so it is critical that Physician Compare incorporate the full scope of performance.

However, many commenters opposed adding Medicare Advantage data due to concerns with data accuracy and comparison to FFS quality data. One commenter suggested alignment of physician and physician group quality measures across traditional FFS Medicare, Medicare ACOs, and Medicare Advantage. Another commenter asked where information on Medicare Advantage professionals would be obtained and how often the database would be updated. Commenters were concerned that adding Medicare Advantage data to Physician Compare would be complicated and difficult for both consumers and health care professionals to understand. One commenter asked for additional information on how this information would be messaged to the consumer.

Response: We appreciate that there are many health care professionals providing services through Medicare Advantage, and consumers have regularly indicated an interest in knowing which Medicare Advantage plans, if any, health care professionals on Physician Compare are associated. However, we also appreciate the concerns raised regarding data access and the technical concerns regarding the ability to appropriately link to Plan Finder. We will further evaluate all of the information shared and questions asked concerning the inclusion of Medicare Advantage data, and we will consider these issues for potential future rulemaking.

c. Value Modifier

We also sought comment on including additional VM cost and quality data on Physician Compare. Specifically, we sought 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 sought 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 sought 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 needed time to establish the best method for public reporting and to ensure this information is accurately understood and interpreted by consumers. Therefore, we only sought comment at this time.

The following is a summary of the comments we received regarding potentially including additional VM information on Physician Compare in the future.

Comment: A few commenters supported potentially including an indicator of downward and neutral adjustments under the VM on physician profile pages in the future. Several commenters opposed including additional VM data on profile pages because of concerns around the current VM methodology, the complexity of the program, and concerns about the meaningfulness of the cost and quality composite scores to consumers. One commenter noted that the VM cost and quality composites will be of limited future utility due to the movement towards MIPS.

Response: As noted above, we appreciate the concerns raised about sharing VM data with consumers, and we acknowledge that the payment adjustment under the VM end after CY 2018. We will further review all comments and suggestions regarding this data and consider for potential future rulemaking.

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 sought

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 sought comment on adding these data to Physician Compare, to the extent it is feasible and appropriate. Prior to considering a formal proposal, we 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 sought comment at this time.

The following is a summary of the comments we received regarding possible future inclusion of Open Payments data on Physician Compare.

Comment: Commenters both supported and opposed making Open Payments data available on Physician Compare. Some commenters supported public access to Open Payments data, but opposed adding it to Physician Compare. Some commenters supported linking to the existing Open Payments website, and others noted that the data are already publicly available so adding these data to Physician Compare is redundant. Several commenters urged CMS to provide context for the data to ensure the data are interpreted correctly or to include general information regarding Open Payments rather than the actual Open Payments data. A commenter urged CMS should make clear that manufacturers are not responsible for Physician Compare data and physicians can only log complaints about Open Payments data through the dispute and correction process applicable to the Open Payments program. One commenter suggested establishing additional nature of payment categories for (i) stock option buy outs and (ii) transfers of value not otherwise covered by the existing nature of payment categories. Many commenters noted that Physician Compare serves a different purpose than the Open Payments website and it would be misleading to include this information on Physician Compare as it is

unrelated to the quality of care. Commenters were also concerned with the accuracy of Open Payments data.

Response: We understand that Open Payments data are different from the quality of care data included on Physician Compare, and we appreciate that these data require context to be fully understood. As noted, we do continue to test these data with consumers, and we will take the comments and recommendations provided under consideration and if appropriate, address in possible future rulemaking.

e. Measure Stratification

Finally, we sought comments on including individual EP and group practice level quality measure data stratified by race, ethnicity, and gender on Physician Compare, if feasible and appropriate (that is, statistically appropriate, etc.). By stratification, we mean that we would 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 sought 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 websites and other dissemination strategies (see section 4302 of the Affordable Care Act)

The following is a summary of the comments we received about including individual EP and group practice level quality measure data stratified by race, ethnicity, and gender on Physician Compare.

Comment: Commenters who supported stratifying measures noted that this information is important in determining and tracking health equity, increasing transparency and

accountability, and helping identify and reduce known and persistent health care disparities. Some commenters also noted this would allow consumers to make informed choices based on their preferences and give stakeholders valuable information on gaps and trends in the system based on demographics. Several commenters suggested including primary language, disability status, gender identity, and sexual orientation could also add value. Commenters who opposed stratification noted that consumers may misinterpret the data. Other concerns included over-diluting the data, data collection burden, and privacy issues. One commenter noted that it is not the function of Physician Compare to “monitor trends in health equity.” Another commenter noted that calculation of stratified quality data would require significant research to ensure that the information provided was both meaningful and accurate.

Response: As with all items presented for comment only, we will review the comments and suggestions and consider whether these data sets are appropriate for inclusion on Physician Compare. Any data recommended in these areas and found suitable for public disclosure on Physician Compare would be addressed through separate notice-and-comment rulemaking.

5. Additional Comments Received

We received additional comments which are summarized and addressed below.

Comment: Commenters noted that the absence of measure data on Physician Compare due to limited available or meaningful measures may mislead consumers. Commenters requested disclaimers be added or additional education be conducted to explain that there could be the absence of measure data due to measure limitations and not poor quality. Some commenters added that these explanations should be in plain language at a 6th grade reading level. Several commenters expressed concern with publicly reporting any data until measure limitations can be analyzed or addressed. A few commenters recommended language explaining the significance of QCDR reporting.

Response: We understand that the limited availability of PQRS measures may make it

difficult for some specialties to report. We hope that the introduction of additional measures, such as QCDR measures and patient experience measures, will help mitigate concerns regarding quality data availability in the short term. It is important to realize that most searches on Physician Compare are specialty based. If a given specialty does not have measures, users will only evaluate physicians or other health care professionals that do not have measures. This specialty based search can mitigate some of these concerns. Finally, we also understand that disclaimers and other types of explanatory language are necessary to help inform health care consumers as they use the website. We will continue to work to ensure that the language included on Physician Compare addresses the concerns raised and helps users understand that there are a number of reasons a physician or other health care professional may not have quality data on the website. We are continually working to update all language on the website to ensure it is plain language that can be easily understood.

Comment: Several commenters are concerned with the use of physician-centric language in the proposed rule and on Physician Compare, noting that the name of the website could be more inclusive of all eligible health care professionals. One commenter suggested providing information throughout the website about the full array of qualified professionals included on the website. One commenter asked CMS to assure that audiologists are meaningfully represented and can be easily identified by other professionals and patients.

Response: The name of the site is generally specified in section 10331(a)(1) the Affordable Care Act. Throughout the site we do note that both physicians and other health care professionals are available to search and view. If a professional is in approved status in PECOS and has submitted Medicare FFS claims in their name in the last 12 months, they will be included on Physician Compare. They will be listed by the specialty or other health care professional designation that they enrolled under when joining Medicare.

I. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

This section contains the 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 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 continued to focus on alignment as we developed our proposals for the 2018 PQRS payment adjustment.

In addition, please note that, in our quality programs, we have begun 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) suggested that CMS place an emphasis on higher quality measures, such as functional outcome measures. For example, in the PQRS, we 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 proposed 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 Web Interface as the reporting mechanism. In addition, we proposed to continue to require the reporting of at least 1 applicable cross-cutting measure if an EP sees at least 1 Medicare patient. When reporting measures via a QCDR, we emphasized the reporting of outcome measures, as well as resource use, patient experience of care, efficiency/appropriate use, or patient safety measures.

Furthermore, we note that our proposals related to the 2018 PQRS payment adjustment are similar to the requirements we previously established for the 2017 PQRS payment adjustment. We received comments in previous years, as well as during the comment period for the proposed rule, requesting that CMS not make any major changes to the requirements for PQRS, and we believe these final requirements address these commenters' desire for stable

requirements. Indeed, we received many comments related to our proposals for the 2018 PQRS payment adjustment, and we will address those comments with specificity below. Please note, however, that we received comments on the PQRS that were outside the scope of the proposed rule, as they were not related to our specific proposals for the 2018 PQRS payment adjustment. While we will take these comments into consideration, primarily when we begin to develop policies and requirements for the Merit-based Incentive Payment System (or MIPS), we will not specifically respond to those comments here.

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 sought 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(l)(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 employees 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 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 did not propose 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 did not propose to require the collection of these data elements, we solicited comments regarding the facilitators and obstacles providers and vendors may face in collecting and reporting these attributes. Additionally, we solicited 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. 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. We sought 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 noted 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 8:00 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. Although 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.

The following is a summary of the comments we received regarding this proposal:

Comment: We received many comments in support of our proposal to open the QCDR self-nomination period on December 1 of the prior year to allow more time for entities to self-nominate.

Response: Based on the rationale provided and the positive comments we received, we are finalizing this proposal. 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. Please note, however, that the deadline for an entity becoming a QCDR to submit a self-nomination statement is still 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).

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 proposed 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 invited public comment on this proposal.

Comment: Some commenters opposed this proposal. One commenter stated this one-year waiting period ensures that the entity is established and credible. Another commenter expressed concern that we may be including entities that are “untested” should we modify this requirement.

Response: While the commenters’ concerns regarding modifying this requirement are understood, based on our analysis of requests for entities to become a QCDR, we believe that a “waiting period” is not necessary for entities that are in existence as of January 1. From our experience, at least some of the newer entities requesting to become a QCDR were entities that have had previous experience under a formerly existing QCDR. As such, we do not believe a waiting period is necessary. Therefore, based on the rationale provided, we are finalizing this proposal. Therefore, 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).

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 proposed 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 invited but received no public comment on this proposal. We are finalizing 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 proposed 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 measure specifications the entity submitted. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

We solicited and received the following public comment on this issue:

Comment: Commenters generally opposed this proposal. The commenters believed that vendors needed more time than proposed to gather its QCDR measures information. As such, the commenters believe the proposed January 31 date occurs too soon in the year.

Response: We understand the commenters concerns regarding needing more time to gather measures information. However, in order for CMS to more closely analyze these potential QCDR measures due to the issues we have found in the past, we must finalize our January 31 deadline, as proposed. Therefore, we are finalizing our proposal 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), as proposed.

Data Validation Requirements for QCDRs: 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 proposed 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 e-mail to the QualityNet Help Desk at Qnetsupport@sdps.org by **5:00 PM e.s.t. on June 30, 2016**. The e-mail subject should be "PY2015 Qualified Registry Data Validation Execution Report."

We received the following comments on these proposed validation requirements:

Comment: Some commenters opposed these proposed requirements to provide the QCDR the above data for auditing purposes. The commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement

these requirements. Commenters also believed that EP verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements, because QCDRs may have different strategies to meet the data validation requirements. Requiring all QCDRs to collect NPI and tax documentation from each EP as part of a data validation strategy is unduly burdensome.

Response: We understand the commenters' concerns associated with not having received full information from its clients. We note, however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, the vendors have several months, until June 30, 2016, to obtain this information from its clients. We believe this provides vendors with enough time to gather this information. With respect to commenters' belief that EP verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements, while CMS encourages vendors to check the accuracy of the data being submitted to them, we believe it is also necessary for CMS to have the ability to validate the data received. Therefore, based on the rationale provided, we are finalizing these above requirements for data validation, as proposed. Please note that a vendor will, therefore, need to collect all necessary information by June 30, 2016.

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 proposed that QCDRs also have the ability to submit quality measures data for group practices.

We received the following comments on this proposal:

Comment: Commenters were generally supportive of the newly proposed group practice reporting option via a QCDR and its proposed requirements. Some commenters stressed the importance of maintaining and extending use of the QCDR reporting mechanism.

Response: Based on the positive feedback and the rationale provided, we are finalizing this proposal, as proposed.

b. 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 proposed 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 invited and received the following public comment on this proposal.

Comment: Commenters generally supposed our proposal to use a web-based check box mechanism as a way 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, because it is an efficient method to attest.

Response: Based on the comments received and the rationale provided, we are finalizing our proposals related to attestation statements for registries submitting quality measures data, as proposed.

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 proposed 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. We invited but received no public comment on this proposal. Therefore, we are finalizing this proposal 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, as proposed.

Please note that we are finalizing our proposals related to attestation statements for registries submitting quality measures data, as proposed.

Data Validation Requirements for Qualified Registries: 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 proposed 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, NPDES, 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 e-mail to the QualityNet Help Desk at Qnetsupport@sdps.org by 5:00 PM 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 e-mail subject should be "PY2015 Qualified Registry Data Validation Execution Report."

Comment: Some commenters opposed these proposed requirements to provide the above data for auditing purposes. The commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement these requirements.

Response: We understand the commenters concerns associated with the registry not having received full information from its clients. We note, however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, the vendors have several months, until June 30, 2016, to obtain and collect this information from its

clients. We believe this provides vendors with enough time to gather this information.

Therefore, based on the rationale provided, we are finalizing these above requirements for data validation, as proposed.

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 cooperate with this audit process. In order to ensure that CMS has adequate information to perform an audit of a vendor, we proposed 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 (data submission vendor)) 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 invited public comment on these proposals. The following is a summary of the comments we received regarding these proposals.

Comment: Some commenters opposed these proposed requirements that CMS has proposed for auditing purposes. As with the proposed data validation requirements for QCDRs and qualified registries, the commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement these requirements.

Response: We understand the commenters concerns associated with not having received

full information from its clients. We note, however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, we believe these vendors have enough time to gather this information. Therefore, based on the rationale provided, we are finalizing the requirements we proposed for auditing purposes, as proposed. Please note that, as proposed, these requirements will apply to all vendors submitting PQRS data: qualified registries, QCDRs, direct EHR vendors, or DSV vendors.

3. 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. 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 defined that term in the proposed rule, 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 proposed 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 proposed to define that term in this section, 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 requiring reporting of at least 1 cross-cutting measure, we proposed 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 website at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html>.

We solicited and received the following public comments on our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment:

Comment: Commenters generally supported our proposed reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment, primarily because commenters did not want CMS to propose drastic changes to the criteria for satisfactory reporting. Maintaining similar reporting criteria helps EPs and vendors, as they are already familiar with the reporting criteria. Commenters also generally supported continuing use of the claims-based reporting mechanism as an option to meet the criteria for satisfactory reporting under the PQRS.

Response: Based on the rationale provided and the comments received, we are finalizing our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment, as proposed.

b. 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 proposed 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 solicited and received the following public comments on this proposal:

Comment: Some commenters supported our proposed requirement for satisfactory reporting for the 2018 PQRS payment adjustment via the EHR reporting mechanism. One commenter supported our proposal to keep the requirements similar to the requirement for satisfactory reporting for the 2017 PQRS payment adjustment, as well as our proposal to align reporting options with the CQM component of the EHR Incentive Program.

Response: We appreciate the commenters' positive feedback on this proposal. Based on the rationale provided and the comments received, we are finalizing our proposed satisfactory reporting criteria for individual EPs reporting via direct EHR product and EHR data submission vendor product for the 2018 PQRS payment adjustment, as proposed.

c. 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 proposed 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 solicited and received the following public comment on our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment:

Comment: Commenters generally supported our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment, primarily because commenters did not want CMS to propose drastic changes to the criteria for satisfactory reporting. Commenters stated that maintaining similar reporting criteria helps EPs and vendors, as they are already familiar with the reporting criteria.

Response: Based on the comments received and for the rationale provided, we are

finalizing our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment, as proposed.

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. Criterion for the Satisfactory Participation for Individual EPs in a QCDR for the 2018 PQRS payment adjustment

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 proposed 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 of the 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 solicited and received the following public comments on this proposal:

Comment: We received many comments generally in support of the QCDR reporting mechanism. Commenters also generally supported our proposed criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment, as the commenters urged us not to propose drastic changes to the criteria for satisfactory participation in a QCDR. The commenters were especially concerned with not making drastic changes to the QCDR option, as it is the newest reporting option available in the PQRS.

Response: We appreciate the commenters' feedback. Based on the comments received and the rationale provided, we are finalizing the proposed criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment, as proposed.

5. 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.I.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

Explanation of CAHPS for PQRS: 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 website at

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/CMS-Certified-Survey-Vendor.html>.

Requirements for CAHPS for PQRS for the 2016 Reporting Period: 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 proposed to require group practices of 25 or more EPs that register to participate in the GPRO and select the Web Interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRS. We believe this is consistent with our effort to collect CAHPS for PQRS data whenever possible. However, we excluded 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 still proposed to keep CAHPS for PQRS reporting as an option for all group practices. We noted 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 invited and received the following public comment on this proposal:

Comment: One commenter generally supported requiring the administration of the CAHPS for PQRS survey. However, the majority of commenters were opposed to this

requirement. Some commenters oppose requiring the reporting of the CAHPS for PQRs survey. One commenter is particularly concerned with the timing of the release of the final list of vendors approved to administer the CAHPS for PQRs survey for the 2015 reporting period. The list was not released until after the GPRO registration period closed, not providing group practices with enough time to make a full business decision on whether to administer CAHPS for PQRs prior to the close of GPRO registration. Other commenters are concerned with the cost associated with administering the CAHPS for PQRs survey, particularly for smaller group practices.

Response: We understand the commenters' concerns regarding not being able to receive the list of CAHPS for PQRs vendors for the 2015 reporting period until after registration had closed. We will work to make this list available earlier next year. We also understand that the cost of administering the CAHPS for PQRs survey may be burdensome to smaller group practices. Therefore, as a result of the comments, we are modifying this proposal.

First, we are finalizing our proposal to allow all group practices to voluntarily elect to administer the CAHPS for PQRs survey.

Second, regarding our proposal to require group practices of 25 or more EPs that register to participate in the GPRO and select the Web Interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRs, we are not finalizing this proposal with respect to group practices of 25–99 EPs. We are, however, finalizing this proposal with respect to group practices of 100 or more EPs. Thus, we are requiring that, for the reporting periods occurring in 2016, all group practices of 100 or more EPs that register to participate in the GPRO select a CMS-certified survey vendor to report CAHPS for PQRs, regardless of the reporting mechanism the group practice uses. We note that, for reporting periods occurring in

2015, we currently require all group practices of 100 or more EPs that register to participate in the GPRO select a CMS-certified survey vendor to report CAHPS for PQRs, regardless of the reporting mechanism the group practice uses. Therefore, as it was a previously established requirement, and as group practices of 100 or more EPs were logically included in our proposal to require group practices of 25 or more EPs to report CAHPS for PQRs, we believe it was foreseeable that we would finalize this requirement with respect to group practices of 100 or more EPs. We also believe that this modification addresses the commenters' desire to keep the reporting requirements unchanged. As we specify below, since we are not finalizing this proposal with respect to group practices of 25–99 EPs, we will modify our proposed criteria for satisfactory reporting related to requiring the administering of the CAHPS for PQRs survey for group practices of 25—99 EPs.

In addition, we noted 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 provide an adequate sample of the 12-month reporting period.

b. Criteria for Satisfactory Reporting on PQRs Quality Measures Via the 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 Web Interface (see Table 51 at 79 FR 67797) – we proposed 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 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 Web Interface. Although the criteria proposed above are specified for groups practices of 25 or more EPs, please note that, given our finalized requirement that group practices of 100 or more EPs report the CAHPS for PQRS survey (rather than group practices of 25 or more EPs, as originally proposed), the criteria proposed above would apply to a group practices of 100 or more EPs only if the CAHPS for PQRS survey does not apply to the group practice.

Comment: We solicited and received support for this reporting criterion, mainly because

commenters urged us to keep the reporting requirements unchanged.

Response: We appreciate the commenters' feedback, and, based on the rationale provided and the comments received, are finalizing this proposed criterion, as proposed.

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.I.4.a., we proposed to require that group practices of 25 or more EPs who elect to report quality measures via the 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 proposed 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 Web Interface and for which the CAHPS for PQRS survey applies. Specifically, if a group practice chooses to use the Web Interface in conjunction with reporting the CAHPS for PQRS survey measures, we proposed to specify the following 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 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.

We solicited and received the following public comment on this proposal:

Comment: We did not receive specific comments on this proposed criterion. Please note, however, that we received general comments on the requirement to report CAHPS for PQRS, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQRS only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 25-99 EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the Web Interface and for which the CAHPS for PQRS survey applies, administration of the CAHPS for PQRS survey will be **OPTIONAL** for 2016. Therefore, we are finalizing the following criterion as an option for these group practices if they voluntarily elect to administer the CAHPS for PQRS survey in conjunction with the Web Interface: 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 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 group practices of 100+ EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the Web Interface and for

which the CAHPS for PQRS survey applies, administration of the CAHPS for PQRS survey will be **REQUIRED** for 2016. Therefore, we are finalizing the following criterion for these group practices: 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 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 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 proposed to continue using the attribution methodology used for the VM for the Web Interface beneficiary assignment methodology for the 2018 PQRS payment adjustment and future years. We solicited and

received the following public comment on this proposal:

Comment: One commenter opposed the use of the VM's attribution methodology for purposes of the Web Interface beneficiary assignment and methodology. Specifically, the commenter believed that the VM's attribution methodology penalizes providers for costs beyond their control.

Response: We do not believe that the VM's attribution methodology penalizes providers for costs beyond their control. Please note that the cost measures that must be separately reported for the VM are not reported for the PQRS. Therefore, cost is not associated with the attribution methodology we proposed. Based on the rationale provided, we are finalizing our proposal to continue using the attribution methodology used for the VM for the Web Interface beneficiary assignment methodology for the 2018 PQRS payment adjustment.

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 Web Interface. Therefore, to meet the criteria for satisfactory reporting using the Web Interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable Web Interface measures. If a group practice does not typically see Medicare patients for which the 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 Web Interface, we advise the group practice to participate in the PQRS via another reporting mechanism.

c. 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 proposed 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 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 proposed to implement for registry reporting is a similar process that was established

for reporting periods occurring in 2015 for the 2017 PQR payment adjustment. However, please note that the MAV process for the 2018 PQR 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 invited and received the following public comments on these proposals.

Comment: We received general support for the proposed criteria for satisfactory reporting on individual PQR quality measures for group practices registered to participate in the GPRO via registry for the 2018 PQR payment adjustment. Some commenters specifically supported continued use of the registry-based reporting mechanism. With respect to reporting CAHPS for PQR, please note, we received general comments on the requirement to report CAHPS for PQR, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQR only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 2-99 EPs registered to participate in the GPRO via registry for the 2018 PQR payment adjustment: The administration of the CAHPS for PQR survey is **OPTIONAL**. Therefore, if reporting via registry, these group practices may meet the criteria for satisfactory reporting for the 2018 PQR payment adjustment in one of two ways:

OPTION 1 (group practices that do not voluntarily elect to administer the CAHPS for

PQRS survey in conjunction with the registry): 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 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.

OPTION 2 (group practices that voluntarily elect to administer the CAHPS for PQRS survey in conjunction with the registry)): For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

For group practices of 100+ EPs registered to participate in the GPRO via registry for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is **REQUIRED**. Therefore, if reporting via registry, these group practices must meet the following criterion for satisfactory reporting for the 2018 PQRS payment adjustment: For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

d. 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 proposed 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 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 (since CAHPS for PQRS is in one NQS domain). We invited and received the following public comments on these proposals:

Comment: We received general support for the 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. Some commenters specifically supported continued use of the EHR-based reporting mechanism. With respect to reporting CAHPS for PQRS, please note, we received general comments on the requirement to report CAHPS for PQRS, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQRS only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 2-99 EPs registered to participate in the GPRO via EHR for the

2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is **OPTIONAL**. Therefore, if reporting via EHR, these group practices may meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment in one of two ways:

OPTION 1 (group practices that do not voluntarily elect to administer the CAHPS for PQRS survey in conjunction with EHR): 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.

OPTION 2 (group practices that voluntarily elect to administer the CAHPS for PQRS survey in conjunction with EHR): For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

For group practices of 100+ EPs registered to participate in the GPRO via EHR for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is **REQUIRED**. Therefore, if reporting via EHR, these group practices must meet the following criterion for satisfactory reporting for the 2018 PQRS payment adjustment: For the 12-month

reporting period for the 2018 PQRS payment adjustment, 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.

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 requires 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. Reporting Period for the Satisfactory Participation by Group Practices 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, requires 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 proposed 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 proposed 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 invited 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.

The following is a summary of the comments we received regarding our proposal.

Comment: Commenters generally supported the proposed 12-month 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, as it is consistent with the reporting period for other criteria for satisfactory reporting, as well as satisfactory participation in a QCDR in the PQRS.

Response: As a result of the supportive comments, we are finalizing this reporting period, as proposed. Therefore, we are revising §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.

g. 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 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 proposed 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.

We solicited and received the following public comments on these proposals:

Comment: Commenters generally supported the option to report quality measures data via a QCDR as a group practice. One commenter opposed the proposal to require group practices using a QCDR to report on at least 9 measures. The commenter noted that when the QCDR option was first introduced to as a reporting method for individuals, EPs were only required to report at least three measures.

Response: We appreciate the commenters' concerns regarding the requirement to report at least 9 measures. However, we believe that group practices should be required to report on the

same amount of measures as an individual EP. Based on the positive feedback and the rationale provided, we are finalizing the proposed criterion for satisfactory participation in a QCDR for group practices registered to participate in the GPRO via a QCDR for the 2018 PQRS payment adjustment, as proposed.

Tables 27 and 28 reflect our criteria for satisfactory reporting – or, in lieu of satisfactory reporting, satisfactory participation in a QCDR – for the 2018 PQRS payment adjustment:

TABLE 27: Summary of 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 28: Summary of 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)	25–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply)	Individual GPRO Measures in the Web Interface	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.
12-month (Jan 1– Dec 31, 2016)	25–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies)	Individual GPRO Measures in the Web Interface + CAHPS for PQRS	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 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 Web Interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the Web Interface measures.
12-month (Jan 1– Dec 31, 2016)	2–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply)	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.

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
12-month (Jan 1– Dec 31, 2016)	2—99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies)	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—99 EPs; 100+ EPs (if CAHPS for PQRS does not apply)	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—99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies)	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.
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 a “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.

As such, we may exercise our authority under section 1848(k)(2)(C)(ii) of the Act to propose and finalize a measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

a. PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section discusses the inclusion or removal of measures in PQRS for 2016 and beyond. We classified all 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.

In addition, CMS considers the MAP's recommendations as part of the comprehensive assessment of each measure considered for inclusion in the program. Additional elements under consideration include a measure's fit within the program, if a measure fills clinical gaps, changes or updates to clinical guidelines and other program needs. As such, while CMS strongly considers the MAP's recommendations, MAP support is not required for inclusion in PQRS.

Please note that the PQRS quality measure specifications for any given PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the 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 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 noted 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 used 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 noted that the NQF process incorporates an opportunity for public comment and engagement in the measure

maintenance process. We revised the Specifications Manual and posted notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates are also available on the CMS PQRS website 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 31, we proposed 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 noted 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 proposed to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. We stated that we would discuss any such instances in the CY 2016 PFS final rule with comment period.

In addition, we noted 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 began to group our final measures available for reporting according to specialty. The current listing of our measures by specialty can be found on our website 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.

b. 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_CrosscuttingMeasures_12172014.pdf. In Table 29, we proposed the following measures to be added to the current PQRS cross-cutting measure set. Please note that our rationale for each of these measures is found below the measure description. We solicited and received public comments on these measures. A summary of the comments, our responses, as well as final decisions are in Table 29. Please note that these proposed measures in Table 30 are in addition to the 19 previously finalized cross-cutting measures. As such, for 2016, there will be a total of 23 cross-cutting measures in PQRS.

TABLE 29: Individual Quality Cross-Cutting Measures for the PQRS to be Available for Satisfactory Reporting via Claims, Registry, and EHR beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^v	Measure Steward	Other Quality Reporting Programs
Measures Finalized as Proposed					
2152/ 431	N/A	Community/ Population Health	<p>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.</p> <p>This measure was 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</p>	American Medical Association – Physician Consortium for Performance Improvement	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^v	Measure Steward	Other Quality Reporting Programs
			<p>document to ensure maintenance for this risk, and is applicable to most Medicare adult patients.</p> <p>While several commenters agreed this measure was appropriately classified as cross-cutting, one commentator suggested this measure be delayed for implementation as cross-cutting to allow providers time to standardize documentation processes. CMS continues to believe this is a broadly applicable measure reportable by several provider types and should be relatively easy for providers to document. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.</p>		
2372/ 112	125v4	Effective Clinical Care	<p>Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.</p> <p>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).</p> <p>This measure was 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.</p> <p>Several commenters agreed this measure was appropriately classified as cross-cutting. One commenter suggested that designating this measure as cross-cutting “may be viewed as an endorsement of a reduction in the frequency of screening and may compromise patient care”. CMS believes that designating a measure as cross-cutting would not impact patient access to appropriate care. CMS believes that providers should adhere to clinical guidelines and not treat patients based on quality measures. CMS continues to believe this is a broadly applicable measure reportable by a number of providers. For these reasons, CMS is finalizing its proposal to include this measure as cross-cutting beginning in 2016 for PQRS.</p>	National Committee for Quality Assurance	ACO/ MU2
0101/ 154	N/A	Patient Safety	<p>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.</p> <p>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.</p> <p>This measure was proposed as a cross-cutting measure for PQRS for CY 2016 PFS as it is applicable to a variety of physician specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.</p>	National Committee for Quality Assurance/ American Medical Association – Physician Consortium for Performance Improvement	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Other Quality Reporting Programs
0101/ 155	N/A	Communication and Care Coordination	<p>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.</p> <p>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 (<i>77 FR 69232</i>). In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting.</p> <p>This measure was proposed as a cross-cutting measure for PQRS for CY 2016 as it is applicable to a variety of physician specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.</p> <p>Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.</p>	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. New PQRS Measures Available for Reporting for 2016 and Beyond and Changes to Existing PQRS Measures

Table 30 contains additional measures we proposed to include in the PQRS measure set for CY 2016 and beyond. We 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 proposed 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, although we take these recommendations into consideration, in these instances, we believe the rationale provided for the addition of a measure outweighs the MAP’s recommendation.

TABLE 30: 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 ^Y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
Measures Finalized as Proposed or with Modifications												
N/A/ 403	N/A	Person 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 or 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.	Several commenters supported the inclusion of this measure in PQRS. However, one commenter was concerned the nephrologist will have to engage palliative care providers prior to the decision to withdraw from dialysis and that not all patients who are referred to hospice choose to immediately withdraw from dialysis. CMS continues to believe this is a valuable measure that fills a clinical gap in the program. As indicated in the measure specification, this measure is assessing if a referral to hospice is made for those patients who withdraw from dialysis and as such CMS does not believe palliative care must be engaged prior to this decision. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	Renal Physicians Association/ American Medical Association – Physician Consortium for Performance Improvement			X			
N/A/ 439	N/A	Efficiency and Cost Reduction	Age Appropriate Screening Colonoscopy: The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	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	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Unnecessary Screening Colonoscopy in Older Adults” in Table 23 at 80 FR 41832 through	American Gastroenterologi- cal Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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.	41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Another commenter was concerned with CMS not proposing this measure for claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenter's concerns and believes that exclusion of the claims-based reporting option will not negatively impact a significant number of providers reporting this measure. For these reasons, CMS is finalizing this measure for registry reporting in 2016 PQRS.							

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 404	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.	Several commenters were concerned with this measure proposed as registry only reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters' concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS's goal to lower the data error rate and decrease provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	American Society of Anesthesiologist s			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 421	N/A	Effective Clinical Care	<p>Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal: Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.</p>	<p>Encourage Continued Development</p> <p>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.</p>	<p>The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Percentage of Patients with a Retrievable Inferior Vena Cava (IVC) Who Are Appropriately Assessed for Continued Filtration or Device Removal” in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. CMS received supportive comments regarding the inclusion of this measure in PQRS. CMS is finalizing this measure for reporting in 2016 PQRS.</p>	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 405	N/A	Effective Clinical Care	<p>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:</p> <ul style="list-style-type: none"> •Liver lesion ≤ 0.5 cm •Cystic kidney lesion < 1.0 cm •Adrenal lesion ≤ 1.0 cm 	<p>Encourage Continued Development</p> <p>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.</p>	<p>Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	American College of Radiology	X		X			
N/A/ 406	N/A	Effective Clinical Care	<p>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</p>	<p>Encourage Continued Development</p> <p>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</p>	<p>Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a</p>	American College of Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	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.	specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 407	N/A	Effective Clinical Care	<p>Appropriate Treatment of MSSA Bacteremia: Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.</p>	<p>2013 MAP stated there was “Insufficient Information” and provided no further comments.</p> <p>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.</p>	<p>The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure represents a strong clinical need and PQRS measure gap. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	Infectious Diseases Society of America	X		X			
N/A/ 408	N/A	Effective Clinical Care	<p>Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during</p>	<p>Conditional Support</p> <p>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</p>	<p>The title and description of this measure has been updated since appearing in the CY 2016 PFS Proposed rule (originally entitled “Chronic Opioid Therapy Follow-up Evaluation” in Table 23 at 80 FR 41832 through 41857) and</p>	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			Opioid Therapy documented in the medical record.	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 measure promotes patient safety within PQRS.	conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this is an analytically robust and clinically sound measure that identifies the importance of patient safety. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 409	N/A	Effective Clinical Care	Clinical Outcome Post Endovascular Stroke Treatment: Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	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.	While some commenters supported the inclusion of this measure in the program, one commenter recommended CMS exclude this measure from the program until it has been fully specified and validated. In addition, this commenter maintained this measure should be risk-adjusted for those providers who care for the sickest patients. Measures finalized for inclusions in the program have undergone feasibility, validity and reliability testing. Additionally, measures within PQRS are fully specified prior to implementation. CMS continues to believe this measure assesses improvement based on the therapy	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
					provided. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							
0711 / 411	N/A	Communication and Care Coordination	Depression Remission at Six Months: Adult patients age 18 years 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.	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.	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this is an important outcome measure for mental health providers. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Minnesota Community Measurement			X			
N/A/ 412	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 Opioid Therapy 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	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Several commenters supported the inclusion of this measure in PQRS. One commenter suggested modifications to the measure specification. CMS uses the measure specifications as approved by the measure stewards and owners. CMS is finalizing this measure for reporting in 2016 PQRS.	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				clinically robust and not duplicative of any measures in the PQRS.								
N/A/ 413	N/A	Effective Clinical Care	Door to Puncture Time for Endovascular Stroke Treatment: Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	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 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.	Several commenters supported the inclusion of this measure in PQRS. One commenter maintained this measure needs further development and validation prior to implementation, noting the target time may be too long, few facilities will have sufficient volume, and that CMS should consider how transfers are handled. CMS appreciates this commenter’s concerns. However, CMS continues to believe this is a relevant measure that fills a clinical gap in the program. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Society of Interventional Radiology			X			
N/A/ 415	N/A	Efficiency and Cost Reduction	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18	Encourage Continued Development Although this measure is not NQF-endorsed, we are exercising our	The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Imaging in	American College of Emergency Physicians	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			<p>Years and Older: Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.</p>	<p>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.</p>	<p>Adult Emergency Department (ED) Patients with Minor Head Injury” in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS is finalizing this measure for reporting in 2016 PQRS.</p>							
N/A/ 416	N/A	Efficiency and Cost Reduction	<p>Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years: Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head</p>	<p>Encourage Continued Development</p> <p>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</p>	<p>The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Imaging in Pediatric ED Patients Aged 2 through 17 Years with Minor Head Injury” in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most</p>	American College of Emergency Physicians	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the PECARN prediction rules for traumatic brain injury.	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.	current measure specification. Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure is clinically robust, analytically feasible and fills a clinical gap as it addresses the importance of radiation safety within the adolescent population. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 414	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,	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	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	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.	inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap and addresses the importance of patient safety. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
0053 /418	N/A	Effective Clinical Care	Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.	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 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.	Although no comments were received regarding the proposal of this measure, CMS continues to believe that NQF # 0053 represents a more harmonized and up-to-date measure than NQF # 0048, which we are removing in Table 32 of this final rule with comment period. CMS is finalizing this measure for reporting in 2016 PQRS.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 419	N/A	Efficiency and Cost Reduction	<p>Overuse Of Neuroimaging For Patients With Primary Headache And A Normal Neurological Examination: Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered.</p>	<p>Conditional Support</p> <p>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.</p>	<p>The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure fulfills a clinical gap as it addresses the overuse of neuroimaging and its relation to patient safety. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	American Academy of Neurology	X		X			

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N/A/ 428	N/A	Effective Clinical Care	<p>Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence: Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines.</p>	<p>Conditional Support</p> <p>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.</p>	<p>The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Preoperative Assessment of Occult Stress Urinary Incontinence Prior to any Pelvic Organ Prolapse Repair” in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as it addresses patients who do not receive preoperative assessment of occult stress urinary incontinence prior to pelvic organ prolapse repair. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	American Urogynecologic Society			X			

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N/A/ 429	N/A	Patient Safety	Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy: Percentage of patients who are screened for uterine malignancy 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.	The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Preoperative Exclusion of Uterine Malignancy Prior to any Pelvic Organ Prolapse Repair" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure fills a clinical gap as it addresses patients who receive preoperative exclusion of uterine malignancy prior to any pelvic organ prolapse repair. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American Urogynecologic Society	X		X			
2063 / 422	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 hysterectomy for pelvic organ prolapse.	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	This measure is now NQF #2063. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure fills a clinical gap as it addresses injury during hysterectomy procedures. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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.								
0465 / 423	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.	Commenters supported the concept of this measure but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. This measure fills a clinical gap as it promotes prevention of secondary vascular disease beyond surgery. CMS is finalizing this measure for reporting in 2016 PQRS.	Society for Vascular Surgeons	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
2671 / 424	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.	This measure is now NQF #2671. CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	American Society of Anesthesiologists			X			
N/A/ 425	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	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as photodocumentation of cecal intubation aids in the prevention of colon cancer. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American College of Gastroenterology / American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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 of colon cancer. Additionally, this measure would be applicable for gastroenterology specialists to report.								
N/A/ 426	N/A	Communication and Care Coordination	Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU): Percentage of patients, regardless of age, 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	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Several commenters CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. . Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these	American Society of Anesthesiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				practice in anesthesia.	measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 427	N/A	Communication and Care Coordination	<p>Post-Anesthetic Transfer of Care: 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.</p>	<p>Encourage Continued Development</p> <p>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.</p>	<p>The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Post-Anesthetic Transfer of Care Measure: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU)” in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward’s most current measure specification. CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters’ concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS’s goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	American Society of Anesthesiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 430	N/A	Patient Safety	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy: Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic 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.	CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	American Society of Anesthesiologists			X			
2152 / 431	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.	Encourage Continued Development This measure will replace PQRS #173 "Preventive Care and 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.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe it is a more clinically robust measure for unhealthy alcohol use than the measure it replaces, PQRS #173 "Preventive Care and Screening Unhealthy Alcohol Use-Screening." For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American Medical Association – Physician Consortium for Performance Improvement			X			X
N/A/	N/A	Patient Safety	Proportion of	Conditional	Several commenters	American			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
432			<p>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.</p>	<p>Support</p> <p>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.</p>	<p>supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.</p>	<p>Urogynecologic Society</p>						
N/A/ 433	N/A	Patient Safety	<p>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 time of index surgery that is recognized intraoperative or within 1 month after surgery.</p>	<p>Conditional Support</p> <p>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</p>	<p>Several commenters supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.</p>	<p>American Urogynecologic Society</p>			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [†] (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.								
N/A/ 434	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.	Commenters supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.	American Urogynecologic Society			X			
N/A/ 410	N/A	Person and Caregiver-Centered Experience and Outcomes	Psoriasis: Clinical Response to Oral Systemic or Biologic Medications: Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an	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	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Clinical Response to Oral Systemic or Biologic Medications" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters	American Academy of Dermatology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	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.	supported the inclusion of this measure in PQRS. CMS continues to believe this outcome measure represents a domain gap in the program. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 435	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.	Although commenters supported the inclusion of this measure in PQRS, a commenter requested the tool used to measure quality of life be specified. CMS relies on the information and guidance of subject matter experts and measure specifications as approved by the measure stewards and owners, when implementing measures in PQRS. The measure specification does not specify which tool should be used to allow for flexibility by Eligible Professionals to choose the tools that work best in their clinical settings. CMS is finalizing this measure for reporting in 2016 PQRS.	American Academy of Neurology	X		X			
N/A/ 436	N/A	Effective Clinical Care	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques: Percentage of final	This measure appeared on the 2013 MUC list. MAP's recommendation in their 2014 report was	Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain	American College of Radiology/ American Medical Association – Physician	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			<p>reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used:</p> <ul style="list-style-type: none"> Automated exposure control Adjustment of the mA and/or kV according to patient size Use of iterative reconstruction technique 	<p>Support.</p> <p>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.</p>	<p>NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure fills a current gap within the program for patient safety and targets an under represented provider group. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.</p>	<p>Consortium for Performance Improvement / National Committee for Quality Assurance</p>						
1523 / 417	N/A	Patient Safety	<p>Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive: Percentage of patients undergoing open repair of abdominal aortic aneurysms (AAA) who are discharged alive.</p>	<p>Support</p> <p>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</p>	<p>This measure is now NQF #1523. Further, title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "In-Hospital Mortality Following Elective Open Repair of AAAs" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification No comments were received regarding the proposal of this measure. CMS continues to believe this outcome measure fills a clinical gap in</p>	<p>Society for Vascular Surgeons</p>			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				it assesses mortality rate in AAA repair. This measure is clinically sound, analytically feasible, and is reportable by both general surgeons and vascular surgeons.	the program as it assesses mortality rate in AAA repair. CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 437	N/A	Patient Safety	Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure: Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	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 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.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as it addresses unplanned complications in major amputation or surgical bypass. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Society of Interventional Radiology	X		X			
N/A/ 438	N/A	Effective Clinical Care	Statin Therapy for the Prevention and Treatment of	Encourage Continued Development	Several commenters support the concept of this measure, noting it fills an	Centers for Medicare & Medicaid Services/			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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			<p>Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:</p> <ul style="list-style-type: none"> Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR Adults aged ≥ 21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL 	<p>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.</p>	<p>important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator. This measure reflects CMS's effort to adhere to current clinical guidelines. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. CMS also appreciates commenters concern regarding broadening the measure to include other therapies beyond statin, however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One commenter also</p>	<p>Mathematica/ Quality Insights of Pennsylvania</p>						

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
					<p>expressed concern that this measure requires further testing and may not cover all components of the current guidelines. CMS requires that all measures included in the program undergo feasibility, validity and reliability testing. Further, CMS recognizes the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program. CMS may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. After further review, CMS determined this measure is not analytically feasible to report through claims. Therefore, CMS is finalizing its proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS.</p>							
N/A/ 420	N/A	Effective Clinical Care	<p>Varicose Vein Treatment with Saphenous Ablation: Outcome Survey: Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a</p>	<p>Encourage Continued Development</p> <p>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</p>	<p>The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Percentage of Patients Treated for Varicose Veins who are Treated with Saphenous Ablation and Receive an Outcomes Survey Before and after Treatment" in Table 23 at 80 FR 41832 through 41857) and</p>	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			disease specific patient reported outcome survey instrument after treatment.	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.	conforms to the measure steward's most current measure specification. CMS received supportive comments regarding the inclusion of this measure in the program. CMS continues to believe the measure provides a measurement tool for successful varicose vein therapy. CMS is finalizing this measure for reporting in 2016 PQRS.							
Measures Not Finalized as Proposed												
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 reportable by EPs that provide care to pediatric	One commenter was concerned with CMS' proposal to add this measure to 2016 PQRS, noting that this measure is not ready for implementation. After further consideration, CMS agrees with the commenter and believes this measure requires further testing and may not be feasible to be reported via Registry. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	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 ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	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.	patients. 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 high-risk elderly patients with cognitive impairment. This measure supports a variety of EPs that support this high-risk Medicare patient population.	Some commenters supported CMS’ proposal to add this measure to 2016 PQRS, noting that the measure aligns with current clinical guidelines. CMS found that this measure was developed and tested for eCQMs only. Furthermore, PQRS would be out of alignment with Meaningful Use should this measure be finalized as a Registry measure. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	Centers for Medicare & Medicaid Services			X			
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	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	While one commenter supported the intent of this measure, they urged CMS to include this measure only when electronic medical record systems are able to support this measure. After further review, CMS found that this measure was developed and tested for eCQMs only. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			to communicate with the patient's primary care provider or their specialist about the patient's visit to the emergency department.	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.								
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 care proxy during the measurement period.	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 cognitive impairment care to Medicare patients. This measure promotes the clinical concept of interdisciplinary communication within the PQRS as a whole.	Some commenters supported the inclusion of this measure. However, after further review, CMS found that this measure was developed and tested for eCQMs only. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	Centers for Medicare & Medicaid Services			X			
N/A/	N/A	Patient Safety	Extravasation of	Encourage	One commenter	American	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A			<p>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.</p>	<p>Continued Development</p> <p>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.</p>	<p>supported CMS' proposal to add this measure to 2016 PQRS, noting that they agree with adopting additional measures addressing imaging services. However, the measure steward of this measure withdrew support for this measure, indicating data suggest that the variation/gap in care does not justify continuation of the measure. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.</p>	College of Radiology						

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
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.	While some commenters supported the inclusion of this measure in PQRS, after further review CMS determined this measure would be considered a basic standard of care and thus would not fill a quality gap in the program. For this reason, CMS is not finalizing this measure for reporting in 2016 PQRS.	American College of Gastroenterology / American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy	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	Commenters supported CMS’ proposal to add this measure to 2016 PQRS, noting that the measure is clinically sound and represents an important screening concept. However, after further consideration, CMS determined this measure requires additional testing. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	Centers for Disease Control and Prevention	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ^y (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				<p>partnership. This measure is clinically-sound and represents an 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.</p>								
N/A/ N/A	N/A	Effective Clinical Care	<p>HIV Screening of STI patients: Percentage of patients diagnosed with an acute STI who were tested for HIV.</p>	<p>Encourage Continued Development</p> <p>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</p>	<p>Commenters supported CMS' proposal to add this measure to 2016 PQRS, noting that the measure is clinically sound and represents an important screening concept. However, after further review, CMS determined the measure, in its current form, needs further development prior to implementation. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.</p>	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				reportable by a variety of specialists, including primary care physicians, family practice doctors, OB-GYNs, urologists, and internal medicine physicians.								

¥ 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 31, we provided our proposals for a NQS domain change for measures that are currently available for reporting under the PQRS.

TABLE 31: 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
Measures Finalized as Proposed				
0089/ 019	142v4	Effective Clinical Care (PFS 2015 final rule)	Communication and Care Coordination	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Commenters supported the domain change for PQRS #019 from Effective Clinical Care to Communication and Care Coordination. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.</p>
0420/ 131	N/A	Community/ Population Health (PFS 2013 final rule)	Communication and Care Coordination	<p>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.</p> <p>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. 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).</p> <p>CMS proposed 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.</p> <p>No comments were received for the proposed domain change for PQRS #131 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.</p>

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
0643/ 243	N/A	Effective Clinical Care (PFS 2015 final rule)	Communication and Care Coordination	<p>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.</p> <p>This measure has been reportable through PQRS for 4 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69245).</p> <p>CMS proposed 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.</p> <p>One commentor supported the proposed domain change for PQRS #243 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.</p>
N/A/ 330	N/A	Effective Clinical Care (PFS 2015 final rule)	Patient Safety	<p>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.</p> <p>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 74638).</p> <p>CMS proposed 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 occurrence of a health outcome that results from the absence of appropriate structures or processes.</p> <p>No comments were received for the proposed domain change for PQRS #330 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.</p>
N/A/ 378	75v4	Effective Clinical Care (PFS 2015 final rule)	Community/ Population Health	<p>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</p> <p>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).</p> <p>CMS proposed 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.</p> <p>No comments were received for the proposed domain change for PQRS #378 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.</p>

¥ 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 32, we proposed to remove the following measures from reporting under the PQRS.

TABLE 32: Measures for Removal from the Existing PQRS Measure Set Beginning in 2016

NQF/ PQRS	NQS Domain	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
Measures Finalized as Proposed											
0241/ 033	Effective Clinical Care	<p>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.</p> <p>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).</p> <p>CMS proposed removal in the CY 2016 PFS proposed rule as this measure is duplicated within the PQRS with current measure, Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy (PQRS#32).</p> <p>Some commenters disagreed with CMS’ proposal to remove PQRS #033 based on the rationale that PQRS #033 is duplicative of PQRS #032 (Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy). Commenters maintained the denominator of this measure is sufficiently different from the denominator of PQRS #032 and that removing this measure may result in inappropriate treatment and increased risk of stroke. CMS believes PQRS #032 is the more broadly applicable measure and patients captured in the denominator of PQRS #033 would also be included in the denominator of PQRS #032, and that #033 therefore remains duplicative. Furthermore, CMS maintains that providers should be providing services and care based on clinical guidelines and not quality measures, and as such CMS does not agree removal of this measure will negatively impact treatment. For these reasons, CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>	American Academy of Neurology			X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^v	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
0048/040	Effective Clinical Care	<p>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.</p> <p>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).</p> <p>CMS proposed 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 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).</p> <p>No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement	X		X					
0323/081	Communication and Care Coordination	<p>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 $spKt/V \geq 1.2$.</p> <p>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).</p> <p>CMS proposed 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</p>	Renal Physicians Association			X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^v	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
		<p>to 100%, suggesting there is no gap in care.</p> <p>Commenters disagreed with CMS' proposal to remove PQRS #081 based on high performance, noting that it measures the core function of dialysis and that adequate dialysis dose is strongly associated with better health outcomes. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>									
0321/ 082	Effective Clinical Care	<p>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 \geq 1.7 per week measured once every 4 months.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Commenters disagreed with CMS' proposal to remove PQRS #081 based on high performance, noting that it measures the core function of dialysis and that adequate dialysis dose is strongly associated with better health outcomes. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>	Renal Physicians Association			X					
N/A/ 172	Effective Clinical Care	<p>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</p>	Society for Vascular Surgeons	X		X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^v	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
		<p>vascular access documented by surgeon to have received autogenous AV fistula.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Two commenters disagreed with CMS' proposal to remove PQRS #172, suggesting this measure has helped foster increased use of Arterial Venous fistula and decreased catheter placement. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>									
AQA Endorse d/ 173	Community/Population Health	<p>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.</p> <p>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 reporting methods.</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>	American Medical Association-Physician Consortium for Performance Improvement			X			X		
N/A/ 193	Patient Safety	<p>Perioperative Temperature Management: Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under</p>	American Society for Anesthesiologists	X		X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^Y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
		<p>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.</p> <p>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).</p> <p>CMS proposed 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 proposed removal due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care.</p> <p>No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>									
0386/ 194	Effective Clinical Care	<p>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.</p> <p>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.</p> <p>CMS proposed 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</p>	American Society of Clinical Oncology			X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^v	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
		<p>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.</p> <p>Some commenters disagreed with the proposal to remove PQRS #194 suggesting “performance on this measure by oncology practices engaged in quality reporting continues to show considerable variation and potential for improvement and retaining this measure will eliminate unwanted variability in performance of this staging measure.” However, CMS continues to believe this measure is a basic standard of care and as such is finalizing its proposal to remove this measure for 2016 PQRS.</p>									
N/A/ 285	Effective Clinical Care	<p>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.</p> <p>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).</p> <p>CMS proposed removal of PQRS #285 in the CY 2016 PFS proposed rule as it was believed that this measure was duplicative of PQRS #134 (Preventive Care and Screening: Screening for Clinical Depression and Follow-up), which includes screening for depression. One commenter requested the standardized screening tool used in PQRS #134 be applicable to patients with dementia if CMS is to finalize its proposal to remove PQRS #285. Although PQRS #134 may not be completely duplicative of PQRS #285, CMS found that #134 is a more clinically robust measure, as it addresses a follow-up plan. CMS is finalizing its proposal to remove PQRS #285 in 2016 PQRS.</p>	American Academy of Neurology / American Psychological Association						X		
0076/34 9	Effective Clinical Care	<p>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, statin medication unless valid contraindication or exception, tobacco-</p>	Minnesota Community Measurement			X					

NQF/ PQRS	NQS Domain	Measure Title and Description ^v	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Reporting Programs
		<p>free status, and daily oral aspirin or anti-platelet use unless valid contraindication or exception.</p> <p>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).</p> <p>CMS proposed removal in the CY 2016 PFS proposed rule as parts of this composite measure are duplicative of Million Hearts measures.</p> <p>One commenter requested CMS retain this measure in the program and instead work with the Million Hearts program to “acknowledge reporting of these clinical areas via the composite rather than the related Million Hearts measures.” CMS appreciates the commenter’s concerns; however, CMS is not able to make changes to the Million Hearts program. This measure continues to be duplicative of the related Million Hearts measures reportable through PQRS, and to maintain alignment with this program, CMS is finalizing its proposal to remove this measure for 2016 PQRS.</p>									
Measures Not Finalized as Proposed											
N/A/ 335	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2014 PFS Final Rule (see Table 52 at 78 FR 74646).</p> <p>CMS proposed removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.</p> <p>Currently, the measure steward is still AMA-PCPI, and the measure is ready for CY 2016 implementation. We have tentatively identified a new measure steward who will maintain the measure for purposes of CY 2017 reporting and beyond, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2016</p>	American Medical Association-Physician Consortium for Performance Improvement			X					

NQE/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		PQRS.								
N/A/ 336	Communication and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2014 PFS Final Rule (see Table 52 at 78 FR 74647).</p> <p>CMS proposed removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.</p> <p>Currently, the measure steward is still AMA-PCPI, and the measure is ready for CY 2016 implementation. We have tentatively identified a new measure steward who will maintain the measure for purposes of CY 2017 reporting and beyond, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2016 PQRS.</p>	American Medical Association-Physician Consortium for Performance Improvement			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 33, we proposed to change the mechanism(s) by which an EP or group practice may report a respective PQRS measure beginning in 2016.

TABLE 33: Existing Individual Quality Measures and those Included in Measures Groups for the PQRS for Which Measure Reporting Updates Will Be Effective Beginning in 2016

NQE/ PQRS	CMS E-Measure ID	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
Measures Finalized as Proposed									

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0088/ 018	167 v3	<p>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.</p> <p>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.</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to add this measure to the Diabetic Retinopathy Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance				X		X
0089/ 019	142 v3	<p>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.</p> <p>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).</p> <p>CMS proposed to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. The physician that manages the ongoing</p>	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 ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		<p>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 – UKPDS).</p> <p>No comments were received regarding the proposal to add this measure to the Diabetic Retinopathy Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>							
0236/ 044	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Several commenters were concerned with this measure proposed to remove the claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters’ concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS’s goal to lower the data error rate and decrease provider burden. For these reasons, CMS is finalizing the removal of the claims reporting option for reporting in 2016 PQRS.</p>	Centers for Medicare & Medicare Services/Quality Insights of Pennsylvania			X			X
0062/ 119	134v 3	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Several commenters were concerned with this measure proposed to remove the claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters’ concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS’s goal to lower</p>	National Committee for Quality Assurance			X	X		X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		the data error rate and decrease provider burden. For these reasons, CMS is finalizing the removal of the claims reporting option for reporting in 2016 PQRS.							
0417/ 126	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Commenters supported the proposal to include this measure in the Diabetes Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	American Podiatric Medical Association			X			X
0056/ 163	123v 4	<p>Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period.</p> <p>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).</p> <p>CMS proposed 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 Program, under which this measure is also available for reporting in 2016, CMS proposed to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.</p> <p>Commenters supported the proposal to remove this measure from the Diabetes Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	National Committee for Quality Assurance				X		
0130/ 165	N/A	<p>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.</p> <p>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).</p>	Society of Thoracic Surgeons						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		<p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>							
0131/ 166	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	Society of Thoracic Surgeons						X
0114/ 167	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p>	Society of Thoracic Surgeons						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.							
0115/ 168	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to make this measure reportable via Measures Groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	Society of Thoracic Surgeons						X
0068/ 204	164v 4	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>Commenters supported the proposal to add this measure to the Cardiovascular Prevention Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	National Committee for Quality Assurance	X		X	X	X	X
0018/ 236	165v 4	<p>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.</p>	National Committee for Quality Assurance	X		X	X	X	X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		<p>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.</p> <p>CMS proposed 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.</p> <p>Commenters supported the proposal to add this measure to the Cardiovascular Prevention Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>							
0022/ 238	156v 4	<p>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.</p> <p>a. Percentage of patients who were ordered at least one high-risk medication.</p> <p>b. Percentage of patients who were ordered at least two different high-risk medications.</p> <p>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.</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to add this measure to the Multiple Chronic Conditions Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	National Committee for Quality Assurance			X	X		X
N/A/ 242	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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</p>	American College of Cardiology/A merican Heart Association/ American Medical Association- Physician Consortium for Performance Improvement						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description ^y	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		<p>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.</p> <p>No comments were received regarding the proposal to make this measure reportable via measures group only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>							
N/A/ 262	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to remove the claims reporting option from this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	American Society of Breast Surgeons			X			
N/A/ 263	N/A	<p>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.</p> <p>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).</p> <p>CMS proposed 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.</p> <p>No comments were received regarding the proposal to remove the claims reporting option from this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	American Society of Breast Surgeons			X			
N/A/ 337	N/A	<p>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.</p>	American Academy of Dermatology			X			X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description [¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		<p>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).</p> <p>CMS proposed 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.</p> <p>One comment was received regarding the proposal to add this measure to the Rheumatoid Arthritis Measures Group suggesting CMS delay this addition for one year to allow providers time to create data collection mechanisms. CMS continues to believe this measure is an appropriate addition to this measures group and that providers can continue to report this measure as an individual measure, if needed. For these reasons, CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>							
0710/ 370	159v 4	<p>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.</p> <p>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 Web Interface reporting method.</p> <p>CMS proposed 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 proposed rule.</p> <p>No comments were received regarding the proposal to add registry as a reporting option for this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.</p>	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 proposed to add the following 3 new measures groups as shown in Tables 34, 35 and 36 that will be available for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provided the PQRS measure numbers for the measures within these measures groups that were previously finalized in the PQRS. New measures within these measures groups that were proposed to be added, as indicated in Table 29, do not have a PQRS number. Therefore, in lieu of a PQRS number, an “NA” is indicated. We solicited and received the following public comments on these proposed measures groups:

- Multiple Chronic Conditions Measures Group: We proposed 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.

Comment: Commenters supported the inclusion of this measure groups in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

- Cardiovascular Prevention Measures Group (Millions Hearts): We proposed 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.

Comment: Commenters supported the inclusion of this measures group in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

- Diabetic Retinopathy Measures Group: We proposed 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.

Comment: Commenters supported the inclusion of this measures group in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

**TABLE 34: 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/ Mathematica/ 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/ Mathematica/ Quality Insights of Pennsylvania
N/A/ 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL <p>This is a new measure described in Table 22 above.</p>	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania

TABLE 35: 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
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 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance

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 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/ Mathematica/ Quality Insights of Pennsylvania

TABLE 36: 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/ Mathematica/ 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/ Mathematica/ 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/ Mathematica/ 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

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 proposed to amend the following previously finalized measures groups (in Table 37 through Table 41) for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provided the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these measures groups that were proposed to be added, as indicated in Table 29, do not have a PQRS number. Therefore, in lieu of a PQRS number, an “NA” is indicated.

TABLE 37: 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.	Centers 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 proposed to amend the Dementia Measures Group for reporting in the PQRS beginning in 2016 by adding Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan (PQRS# 134) and removing Dementia: Screening for Depressive Symptoms (PQRS #285). We solicited and received the following public comment on this measures group.

Comment: One commenter encouraged CMS to retain the nine dementia-specific measures included in the Dementia Measures Group for continued use in the PQRS program even though measures that are not NQF-endorsed are typically removed. The commenter stated that these measures address gaps in the PQRS measure set, reflect the services furnished by a particular specialty, impact chronic conditions, and have a high impact on health care and

support CMS' priorities for improved care quality and efficiency and should be retained in future program years.

Response: In response to the comment requesting CMS retain the nine measures of the Dementia Measures Group, please note CMS proposed to remove only one measure but retain the remaining eight dementia measures in this group. CMS is finalizing its proposal to remove PQRS #285 "Dementia: Screening for Depressive Symptoms" as CMS believes it is duplicative of PQRS #134 "Preventive Care and Screening: Screening for Clinical Depression and Follow-up", which includes screening for depression and is a more robust measure. For this reason, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Dementia Measures Group is shown on Table 38.

TABLE 38: DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND
CMS is finalizing its proposal to add PQRS# 134 Preventive Care and Screening:
Screening for Clinical Depression and Follow-up Plan 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
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/Mathematica/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	American Academy of

NQF/ PQRS	Measure Title and Description	Measure Developer
	disease management and health behavior changes AND referred to additional sources for support within a 12 month period.	Neurology/American Psychological Association

We proposed to amend the Diabetes Measures Group for reporting in the PQRS beginning in 2016 by adding Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (PQRS #126) and removing Diabetes: Foot Exam (PQRS #163). We solicited and received the following public comment on this measures group.

Comment: One commenter supported the proposed changes to the Diabetes Measures Group.

Response: Based on the comments and rationale provided, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Diabetes Measures Group is shown in Table 39.

TABLE 39: DIABETES MEASURES GROUP FOR 2016 AND BEYOND
CMS is finalizing its proposal 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 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months 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

We proposed to amend the Preventative Care Measures Group for reporting in the PQRS beginning in 2016 by adding Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (NQF #2152) and removing Preventive Care and Screening: Unhealthy Alcohol Use – Screening (PQRS #173). We solicited and received the following public comment on this measures group.

Comment: One commenter supported the proposed changes to the Preventative Care Measures Group.

Response: Based on the comments and rationale provided, CMS is finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Preventative Care Measures Group is shown in Table 40.

TABLE 40: PREVENTIVE CARE MEASURES GROUP FOR 2016 AND BEYOND
CMS is finalizing its proposal 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 for
2016 PQRS.

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/039	Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis. The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled “Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older” in Table 29D at 80 FR 41877) and conforms to the measure steward’s most current measure specification.	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 - 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.	Centers for Medicare & Medicaid Services/ Mathematica/ 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/ Mathematica/ 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

NQF/ PQRS	Measure Title and Description	Measure Developer
2152/431	<p>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.</p> <p>This is a new measure described in Table 22.</p>	American Medical Association-Physician Consortium for Performance Improvement

We proposed to amend the Rheumatoid Arthritis Measures Group for reporting in the PQRS beginning in 2016 by adding Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier (PQRS #337). We solicited and received no public comment on this measures group. Therefore, based on the rationale provided, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Rheumatoid Arthritis Measures Group is shown in Table 41.

TABLE 41: RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND
CMS is finalizing its proposal to add PQRS #337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to this measures group for 2016 PQRS.

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 rheumatoid arthritis 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	Centers for Medicare & Medicaid Services/ Mathematica/ 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
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
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 Web Interface

We finalized the measures that are available for reporting in the 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 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 proposed to adopt the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease measure in Table 42 for reporting via the Web Interface beginning in 2016. We solicited and received the following comments on this proposal:

Comment: Several commenters supported the concept of this measure, noting it fills an important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator.

Response: This measure reflects CMS's effort to adhere to current clinical guidelines. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. We also appreciate the commenters concern regarding broadening the measure to include other therapies beyond statin; however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One commenter also expressed concern that this measure requires further testing and may not cover all components of the current guidelines. We require that all measures included in the program undergo feasibility, validity, and reliability testing. Further, we recognize the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program.

After further review, we determined this measure is not analytically feasible to report through claims. The measure owner, CMS, may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. Therefore, we are finalizing our proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS. In addition, we are finalizing this measure under the PREV-13 module. Please note that we do not believe finalizing this measure under the PREV-13 module substantively impacts group practices, as group practices must report on all measures in the Web Interface regardless of the modules in which they are placed. This final change is reflected in Table 42.

TABLE 42: 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
Measure Finalized as Proposed				
Additions				
N/A / 438	PREV	<p>Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:</p> <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL <p>Several commenters support the concept of this measure, noting it fills an important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. CMS is exercising its exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator. This measure reflects CMS’s effort to adhere to current clinical guidelines. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. CMS also appreciates commenters concern regarding broadening the measure to include other therapies beyond statin, however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One commenter also expressed concern that this measure requires further testing and may not cover all components of the current guidelines. CMS requires that all measures included in the program undergo feasibility, validity and reliability testing. Further, CMS recognizes the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program. CMS may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. After further review, CMS determined this measure is not analytically feasible to report through claims. Therefore, CMS is finalizing its proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS.</p>	Centers for Medicare & Medicaid Services/ Mathematica / Quality Insights of Pennsylvania	Shared Savings Program

The FINAL list of all PQRS measures available for reporting in 2016 is below:

TABLE 43: Final Individual Quality Measures and Those Included in Measures Groups for the Physician Quality Reporting System to be Available for Satisfactory Reporting via Claims, Registry, or EHR Beginning in 2016 and Beyond

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0059/ 001	122v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).</p>	National Committee for Quality Assurance
N/A/002	163v4	Effective Clinical Care	<p>Diabetes: Low Density Lipoprotein (LDL-C) Control (<100 mg/dL): Percentage of patients 18–75 years of age with diabetes whose LDL-C was adequately controlled (< 100 mg/dL) during the measurement period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 94 at 77 FR 69209).</p>	National Committee for Quality Assurance
0081/005	135v4	Effective Clinical Care	<p>Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).</p>	American Medical Association- Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
0067/006	N/A	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).</p>	American College of Cardiology/Ameri can Heart Association/ American Medical Association- Physician Consortium for Performance Improvement
0070/007	145v4	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	American Medical Association- Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0083/008	144v4	Effective Clinical Care	<p>Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
0105/ 009	128v4	Effective Clinical Care	<p>Anti-Depressant Medication Management: Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported</p> <p>a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks).</p> <p>b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	National Committee for Quality Assurance
0086/012	143v4	Effective Clinical Care	<p>Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0087/014	N/A	Effective Clinical Care	<p>Age-Related Macular Degeneration (AMD): Dilated Macular Examination: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	American Academy of Ophthalmology
0088/018	167v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0089/019	142v4	Communication and Care Coordination	<p>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</p>	American Medical Association-Physician Consortium for

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			<p>macular or fundus exam at least once within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).</p>	Performance Improvement/ National Committee for Quality Assurance
0268/021	N/A	Patient Safety	<p>Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0271/022	N/A	Patient Safety	<p>Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0239/023	N/A	Patient Safety	<p>Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69218).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0045/024	N/A	Communication and Care Coordination	<p>Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient’s on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69218).</p>	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
0325/032	N/A	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy: 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 antithrombotic at discharge.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69219).</p>	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
0046/039	N/A	Effective Clinical Care	<p>Screening for Osteoporosis for Women Aged 65-85 Years of Age: Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69219).</p>	National Committee for Quality Assurance / American Medical Association- Physician Consortium for Performance Improvement
N/A/041	N/A	Effective Clinical Care	<p>Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).</p>	National Committee for Quality Assurance / American Medical Association- Physician Consortium for Performance Improvement
0134/043	N/A	Effective Clinical Care	<p>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 CABG surgery who received an IMA graft.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).</p>	Society of Thoracic Surgeons
0236/044	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).</p>	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0097/046	N/A	Communicat ion and Care Coordination	<p>Medication Reconciliation Post-Discharge: The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record.</p> <p>This measure is reported as three rates stratified by age group:</p> <ul style="list-style-type: none"> • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older. <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).</p>	National Committee for Quality Assurance / American Medical Association- Physician Consortium for Performance Improvement
0326/047	N/A	Communicat ion and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS</p>	National Committee for Quality Assurance / American Medical Association-

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			Final Rule (see Table 95 at 77 FR 69221).	Physician Consortium for Performance Improvement
N/A/048	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).</p>	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
N/A/050	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).</p>	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
0091/051	N/A	Effective Clinical Care	<p>Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).</p>	American Thoracic Society
0102/052	N/A	Effective Clinical Care	<p>Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1 less than 60% predicted and have symptoms who were prescribed an inhaled bronchodilator.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).</p>	American Thoracic Society
0047/053	N/A	Effective Clinical Care	<p>Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting: Percentage of patients aged 5 years and older with a diagnosis of persistent asthma who were prescribed long-term control medication.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).</p>	American Academy of Allergy, Asthma, and Immunology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0090/054	N/A	Effective Clinical Care	<p>Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain: Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed.</p>	American Medical Association-Physician

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).	Consortium for Performance Improvement/ National Committee for Quality Assurance
0069/065	154v4	Efficiency and Cost Reduction	<p>Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).</p>	National Committee for Quality Assurance
0002/066	N/A	Efficiency and Cost Reduction	<p>Appropriate Testing for Children with Pharyngitis: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).</p>	National Committee for Quality Assurance
0377/067	N/A	Effective Clinical Care	<p>Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemia: Baseline Cytogenetic Testing Performed on Bone Marrow: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0378/068	N/A	Effective Clinical Care	<p>Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0380/069	N/A	Effective Clinical Care	<p>Hematology: Multiple Myeloma: Treatment with Bisphosphonates: Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0379/070	N/A	Effective Clinical Care	<p>Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry: Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
0387/071	140v4	Effective Clinical Care	<p>Breast Cancer: Hormonal Therapy for Stage IC -IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network
0385/072	141v5	Effective Clinical Care	<p>Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients: Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network
N/A/076	N/A	Patient Safety	<p>Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections: Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).</p>	American Society of Anesthesiologists
0395/084	N/A	Effective Clinical Care	<p>Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed within 12 months prior to initiation of antiviral treatment.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterologic Association
0396/085	N/A	Effective Clinical Care	<p>Hepatitis C: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterologic Association
0398/087	N/A	Effective Clinical Care	<p>Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed between 4-12 weeks after the initiation of antiviral treatment.</p>	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).	Improvement/ American Gastroenterologic Association
0653/091	N/A	Effective Clinical Care	<p>Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).</p>	American Academy of Otolaryngology- Head and Neck Surgery
0654/093	N/A	Efficiency and Cost Reduction	<p>Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).</p>	American Academy of Otolaryngology- Head and Neck Surgery
0391/099	N/A	Effective Clinical Care	<p>Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).</p>	College of American Pathologists
0392/100	N/A	Effective Clinical Care	<p>Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).</p>	College of American Pathologists
0389/102	129v5	Efficiency and Cost Reduction	<p>Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).</p>	American Medical Association- Physician Consortium for Performance Improvement
0390/104	N/A	Effective Clinical Care	<p>Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226)</p>	American Medical Association- Physician Consortium for Performance Improvement/ American Urological Association Education and Research

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0104/ 107	161v4	Effective Clinical Care	<p>Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	American Medical Association- Physician Consortium for Performance Improvement
0054/108	N/A	Effective Clinical Care	<p>Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with rheumatoid arthritis and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	National Committee for Quality Assurance
N/A/109	N/A	Person and Caregiver- Centered Experience and Outcomes	<p>Osteoarthritis (OA): Function and Pain Assessment: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	American Academy of Orthopedic Surgeons
0041/110	147v5	Community/ Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	American Medical Association- Physician Consortium for Performance Improvement
0043/111	127v4	Community/ Population Health	<p>Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	National Committee for Quality Assurance
2372/112	125v4	Effective Clinical Care	<p>Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).</p>	National Committee for Quality Assurance
0034/113	130v4	Effective Clinical Care	<p>Colorectal Cancer Screening: Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	National Committee for Quality Assurance
0058/116	N/A	Efficiency and Cost Reduction	<p>Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use: Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0055/117	131v4	Effective Clinical Care	<p>Diabetes: Eye Exam: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	National Committee for Quality Assurance
0066/118	N/A	Effective Clinical Care	<p>Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	American College of Cardiology/American Heart Association/American Medical Association-Physician Consortium for Performance Improvement
0062/119	134v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	National Committee for Quality Assurance
N/A/121	N/A	Effective Clinical Care	<p>Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	Renal Physicians Association
N/A/122	N/A	Effective Clinical Care	<p>Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).</p>	Renal Physicians Association
0417/126	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).</p>	American Podiatric Medical Association
0416/127	N/A	Effective Clinical Care	<p>Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).</p>	American Podiatric Medical Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0421/128	69v4	Community/ Population Health	<p>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</p> <p>Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 kg/m²; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m².</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).</p>	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0419/130	68v5	Patient Safety	<p>Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional 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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).</p>	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0420/131	N/A	Communication and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).</p>	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0418/134	2v5	Community/ Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).</p>	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0650/137	N/A	Communication and Care Coordination	<p>Melanoma: Continuity of Care – Recall System: Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes:</p> <ul style="list-style-type: none"> • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment. <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).</p>	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
N/A/138	N/A	Communication and Care Coordination	<p>Melanoma: Coordination of Care: Percentage of patient visits, regardless of age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).</p>	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0566/140	N/A	Effective Clinical Care	<p>Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).</p>	American Academy of Ophthalmology
0563/141	N/A	Communication and Care Coordination	<p>Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).</p>	American Academy of Ophthalmology
0384/143	157v4	Person and Caregiver-Centered Experience and Outcomes	<p>Oncology: Medical and Radiation – Pain Intensity Quantified: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).</p>	American Medical Association-Physician Consortium for Performance Improvement
0383/144	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).</p>	American Society of Clinical Oncology
N/A/145	N/A	Patient Safety	<p>Radiology: Exposure Time Reported for Procedures Using Fluoroscopy: Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).</p>	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0508/146	N/A	Efficiency and Cost Reduction	<p>Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Mammography Screening: Percentage of final reports for screening mammograms that are classified as “probably benign”.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).</p>	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
N/A/147	N/A	Communication and Care Coordination	<p>Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed.</p>	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	Improvement/ Society of Nuclear Medicine and Molecular Imaging
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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	National Committee for Quality Assurance/ American Medical Association- Physician Consortium for Performance Improvement
0101/155	N/A	Communicat ion 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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	National Committee for Quality Assurance/ American Medical Association- Physician Consortium for Performance Improvement
0382/156	N/A	Patient Safety	Oncology: Radiation Dose Limits to Normal Tissues: Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	American Society for Radiation Oncology
0405/160	52v4	Effective Clinical Care	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	National Committee for Quality Assurance
0056/163	123v4	Effective Clinical Care	Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	National Committee for Quality Assurance
0129/164	N/A	Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	Society of Thoracic Surgeons
0130/165	N/A	Effective Clinical Care	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.	Society of Thoracic Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).	
0131/166	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).</p>	Society of Thoracic Surgeons
0114/167	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).</p>	Society of Thoracic Surgeons
0115/168	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).</p>	Society of Thoracic Surgeons
N/A/176	N/A	Effective Clinical Care	<p>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).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).</p>	American College of Rheumatology
N/A/177	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).</p>	American College of Rheumatology
N/A/178	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).</p>	American College of Rheumatology
N/A/179	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS</p>	American College of Rheumatology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			Final Rule (see Table 95 at 77 FR 69235).	
N/A/180	N/A	Effective Clinical Care	<p>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 \geq 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).</p>	American College of Rheumatology
N/A/181	N/A	Patient Safety	<p>Elder Maltreatment Screen and Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).</p>	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
2624/182	N/A	Communicat ion and Care Coordination	<p>Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).</p>	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0399/183	N/A	Community/ Population Health	<p>Hepatitis C: Hepatitis A Vaccination: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
0659/185	N/A	Communicat ion and Care Coordination	<p>Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).</p>	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/187	N/A	Effective Clinical Care	<p>Stroke and Stroke Rehabilitation: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69237).</p>	American Heart Association/ American Society of Anesthesiologists/ The Joint Commission
0565/191	133v4	Effective Clinical Care	<p>Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69237).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0564/192	132v4	Patient Safety	<p>Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69238).</p>	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0507/195	N/A	Effective Clinical Care	<p>Radiology: Stenosis Measurement in Carotid Imaging Reports: Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69238).</p>	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0068/204	164v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69239).</p>	National Committee for Quality Assurance
0409/205	N/A	Effective Clinical Care	<p>HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69239)</p>	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0422/217	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).</p>	Focus on Therapeutic Outcomes, Inc.
0423/218	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).</p>	Focus on Therapeutic Outcomes, Inc.
0424/219	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).</p>	Focus on Therapeutic Outcomes, Inc.
0425/220	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).</p>	Focus on Therapeutic Outcomes, Inc.
0426/221	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	Focus on Therapeutic Outcomes, Inc.
0427/222	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	Focus on Therapeutic Outcomes, Inc.
0428/223	N/A	Communication and Care Coordination	<p>Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	Focus on Therapeutic Outcomes, Inc.

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
0562/224	N/A	Efficiency and Cost Reduction	<p>Melanoma: Overutilization of Imaging Studies in Melanoma: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
0509/225	N/A	Communication and Care Coordination	<p>Radiology: Reminder System for Screening Mammograms: Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0028/226	138v4	Community/ Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).</p>	American Medical Association-Physician Consortium for Performance Improvement
0018/236	165v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69243).</p>	National Committee for Quality Assurance
0022/238	156v4	Patient Safety	<p>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.</p> <p>a. Percentage of patients who were ordered at least one high-risk medication.</p> <p>b. Percentage of patients who were ordered at least two different high-risk medications.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).</p>	National Committee for Quality Assurance
0024/239	155v4	Community/ Population Health	<p>Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents: Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported.</p> <ul style="list-style-type: none"> - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity. <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).</p>	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
0038/240	117v4	Community/ Population Health	<p>Childhood Immunization Status: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).</p>	National Committee for Quality Assurance
N/A/241	182v5	Effective Clinical Care	<p>Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (< 100 mg/dL): 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 each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).</p>	National Committee for Quality Assurance
N/A/242	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).</p>	American College of Cardiology/Ameri can Heart Association/ American Medical Association- Physician Consortium for Performance Improvement
0643/243	N/A	Communicat ion and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69245).</p>	American College of Cardiology Foundation/ American Heart Association
1854/249	N/A	Effective Clinical Care	<p>Barrett's Esophagus: Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).</p>	College of American Pathologists
1853/250	N/A	Effective Clinical Care	<p>Radical Prostatectomy Pathology Reporting: Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.</p>	College of American Pathologists

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).	
1855/251	N/A	Effective Clinical Care	<p>Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients: This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).</p>	College of American Pathologists
0651/254	N/A	Effective Clinical Care	<p>Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain: Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).</p>	American College of Emergency Physicians
N/A/255	N/A	Effective Clinical Care	<p>Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure: Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).</p>	American College of Emergency Physicians
1519/257	N/A	Effective Clinical Care	<p>Statin Therapy at Discharge after Lower Extremity Bypass (LEB): Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).</p>	Society for Vascular Surgeons
N//A/258	N/A	Patient Safety	<p>Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7): Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).</p>	Society for Vascular Surgeons
N/A/259	N/A	Patient Safety	<p>Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).</p>	Society for Vascular Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/260	N/A	Patient Safety	<p>Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).</p>	Society for Vascular Surgeons
N/A/261	N/A	Communication and Care Coordination	<p>Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness: Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).</p>	Audiology Quality Consortium
N/A/262	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).</p>	American Society of Breast Surgeons
N/A/263	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).</p>	American Society of Breast Surgeons
N/A/264	N/A	Effective Clinical Care	<p>Sentinel Lymph Node Biopsy for Invasive Breast Cancer: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).</p>	American Society of Breast Surgeons
N/A/265	N/A	Communication and Care Coordination	<p>Biopsy Follow-Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).</p>	American Academy of Dermatology
1814/268	N/A	Effective Clinical Care	<p>Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).</p>	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/270	N/A	Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last twelve months.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).</p>	American Gastroenterological Association
N/A/271	N/A	Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment: Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).</p>	American Gastroenterological Association
N/A/274	N/A	Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) for whom a tuberculosis (TB) screening was performed and results interpreted within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).</p>	American Gastroenterological Association
N/A/275	N/A	Effective Clinical Care	<p>Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).</p>	American Gastroenterological Association
N/A/276	N/A	Effective Clinical Care	<p>Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).</p>	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/277	N/A	Effective Clinical Care	<p>Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).</p>	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/278	N/A	Effective Clinical Care	<p>Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).</p>	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/279	N/A	Effective Clinical Care	<p>Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/280	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Academy of Neurology/ American Psychological Association
N/A/281	149v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/282	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Academy of Neurology/ American Psychological Association
N/A/283	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Academy of Neurology/ American Psychological Association
N/A/284	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).</p>	American Academy of Neurology/ American Psychological Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/286	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).</p>	American Academy of Neurology/ American Psychological Association
N/A/287	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).</p>	American Academy of Neurology/ American Psychological Association
N/A/288	N/A	Communication and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).</p>	American Academy of Neurology/ American Psychological Association
N/A/289	N/A	Effective Clinical Care	<p>Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review: All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).</p>	American Academy of Neurology
N/A/290	N/A	Effective Clinical Care	<p>Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).</p>	American Academy of Neurology
N/A/291	N/A	Effective Clinical Care	<p>Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).</p>	American Academy of Neurology
N/A/292	N/A	Effective Clinical Care	<p>Parkinson's Disease: Querying about Sleep Disturbances: All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).</p>	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/293	N/A	Communication and Care Coordination	<p>Parkinson’s Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson’s disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).</p>	American Academy of Neurology
N/A/294	N/A	Communication and Care Coordination	<p>Parkinson’s Disease: Parkinson’s Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson’s disease (or caregiver(s), as appropriate) who had the Parkinson’s disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).</p>	American Academy of Neurology
1536/303	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).</p>	American Academy of Ophthalmology
N/A/304	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).</p>	American Academy of Ophthalmology
0004/305	137v4	Effective Clinical Care	<p>Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported.</p> <p>a. Percentage of patients who initiated treatment within 14 days of the diagnosis.</p> <p>b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).</p>	National Committee for Quality Assurance
0032/309	124v4	Effective Clinical Care	<p>Cervical Cancer Screening: Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).</p>	National Committee for Quality Assurance
0033/310	153v4	Community/Population Health	<p>Chlamydia Screening for Women: Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).</p>	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
0036/311	126v4	Effective Clinical Care	<p>Use of Appropriate Medications for Asthma: Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).</p>	National Committee for Quality Assurance
0052/312	166v5	Efficiency and Cost Reduction	<p>Use of Imaging Studies for Low Back Pain: Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).</p>	National Committee for Quality Assurance
N/A/316	61v5 & 64v5	Effective Clinical Care	<p>Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Test Performed AND Risk-Stratified Fasting LDL-C: Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed AND percentage of patients aged 20 through 79 years who had a fasting LDL-C test performed and whose risk-stratified fasting LDL-C is at or below the recommended LDL-C goal.</p> <p>*There are three criteria for this measure based on the patient’s risk category.</p> <ol style="list-style-type: none"> 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent OR 10-Year Framingham Risk >20% 2. Moderate Level of Risk: Multiple (2+) Risk Factors OR 10-Year Framingham Risk 10-20% 3. Lowest Level of Risk: 0 or 1 Risk Factor OR 10-Year Framingham Risk <10%. <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).</p>	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
N/A/317	22v4	Community/ Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).</p>	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0101/318	139v4	Patient Safety	<p>Falls: Screening for Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period.</p> <p>This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).</p>	National Committee for Quality Assurance
0658/320	N/A	Communicat ion and Care Coordination	<p>Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients: Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74631).</p>	American Medical Association- Physician Consortium for Performance Improvement/ American Gastroenterologic Association/ American Society for Gastrointestinal Endoscopy/ American College of

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
				Gastroenterology
0005 & 0006/321	N/A	Person and Caregiver- Centered Experience and Outcomes	<p>CAHPS for PQRS Clinician/Group Survey:</p> <ul style="list-style-type: none"> • 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 Your to Take Medication as Directed; and • Stewardship of Patient Resources. <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74632).</p>	Agency for Healthcare Research & Quality
N/A/322	N/A	Efficiency and Cost Reduction	<p>Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients: Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74633).</p>	American College of Cardiology
N/A/323	N/A	Efficiency and Cost Reduction	<p>Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI): Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74633).</p>	American College of Cardiology
N/A/324	N/A	Efficiency and Cost Reduction	<p>Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients: Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74634).</p>	American College of Cardiology
N/A/325	N/A	Communicat ion and Care Coordination	<p>Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions: Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by</p>	American Psychiatric Association/Amer ican Medical Association- Physician

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			<p>another clinician with communication to the clinician treating the comorbid condition.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74635).</p>	Consortium for Performance Improvement
1525/326	N/A	Effective Clinical Care	<p>Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy: Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74635).</p>	American College of Cardiology/American Heart Association/American Medical Association-Physician Consortium for Performance Improvement
N/A/327	N/A	Effective Clinical Care	<p>Pediatric Kidney Disease: Adequacy of Volume Management: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74636).</p>	Renal Physicians Association
1667/328	N/A	Effective Clinical Care	<p>Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dl: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74637).</p>	Renal Physicians Association
N/A/329	N/A	Effective Clinical Care	<p>Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74637).</p>	Renal Physicians Association
N/A/330	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74638).</p>	Renal Physicians Association
N/A/331	N/A	Efficiency and Cost Reduction	<p>Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse): Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74639).</p>	American Academy of Otolaryngology-Head and Neck Surgery

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/332	N/A	Efficiency and Cost Reduction	<p>Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74641).</p>	American Academy of Otolaryngology-Head and Neck Surgery
N/A/333	N/A	Efficiency and Cost Reduction	<p>Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74642).</p>	American Academy of Otolaryngology-Head and Neck Surgery
N/A/334	N/A	Efficiency and Cost Reduction	<p>Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74644).</p>	American Academy of Otolaryngology-Head and Neck Surgery
N/A/335	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74646).</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/336	N/A	Communication and Care Coordination	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74647).</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/337	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74648).</p>	American Academy of Dermatology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
2082/338	N/A	Effective Clinical Care	<p>HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).</p>	Health Resources and Services Administration
2083/339	N/A	Effective Clinical Care	<p>Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).</p>	Health Resources and Services Administration
2079/340	N/A	Efficiency and Cost Reduction	<p>HIV Medical Visit Frequency: Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).</p>	Health Resources and Services Administration
N/A/342	N/A	Person and Caregiver- Centered Experience and Outcomes	<p>Pain Brought Under Control Within 48 Hours: Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74651).</p>	National Hospice and Palliative Care Organization
N/A/343	N/A	Effective Clinical Care	<p>Screening Colonoscopy Adenoma Detection Rate Measure: The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74652).</p>	American College of Gastroenterology/ American Gastroenterologic al Association/ American Society for Gastrointestinal Endoscopy
N/A/344	N/A	Effective Clinical Care	<p>Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2): Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74653).</p>	Society for Vascular Surgeons
1543/345	N/A	Effective Clinical Care	<p>Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS): Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74654).</p>	Society for Vascular Surgeons
1540/346	N/A	Effective Clinical Care	<p>Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA): Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74656).</p>	Society for Vascular Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
1534/347	N/A	Patient Safety	<p>Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital: Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74657).</p>	Society for Vascular Surgeons
N/A/348	N/A	Patient Safety	<p>HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate: Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74658).</p>	The Heart Rhythm Society
N/A/350	N/A	Communication and Care Coordination	<p>Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. Nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74661).</p>	American Association of Hip and Knee Surgeons
N/A/351	N/A	Patient Safety	<p>Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74661).</p>	American Association of Hip and Knee Surgeons
N/A/352	N/A	Patient Safety	<p>Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74662).</p>	American Association of Hip and Knee Surgeons
N/A/353	N/A	Patient Safety	<p>Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74662).</p>	American Association of Hip and Knee Surgeons
N/A/354	N/A	Patient Safety	<p>Anastomotic Leak Intervention: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.</p>	American College of Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).	
N/A/355	N/A	Patient Safety	<p>Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).</p>	American College of Surgeons
N/A/356	N/A	Effective Clinical Care	<p>Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).</p>	American College of Surgeons
N/A/357	N/A	Effective Clinical Care	<p>Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI).</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74664).</p>	American College of Surgeons
N/A/358	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74664).</p>	American College of Surgeons
N/A/359	N/A	Communication and Care Coordination	<p>Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74665).</p>	American College of Radiology
N/A/360	N/A	Patient Safety	<p>Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74666).</p>	American College of Radiology
N/A/361	N/A	Patient Safety	<p>Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry: Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS</p>	American College of Radiology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			Final Rule (see Table 52 at 78 FR 74666).	
N/A/362	N/A	Communication and Care Coordination	<p>Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes: Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74667).</p>	American College of Radiology
N/A/363	N/A	Communication and Care Coordination	<p>Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74668).</p>	American College of Radiology
N/A/364	N/A	Communication and Care Coordination	<p>Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74668).</p>	American College of Radiology
N/A/365	148v4	Effective Clinical Care	<p>Hemoglobin A1c Test for Pediatric Patients: Percentage of patients 5-17 years of age with diabetes with a HbA1c test during the measurement period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74669).</p>	National Committee for Quality Assurance
0108/366	136v5	Effective Clinical Care	<p>ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication: Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported.</p> <p>a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase.</p> <p>b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS</p>	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			Final Rule (see Table 52 at 78 FR 74669).	
N/A/367	169v4	Effective Clinical Care	<p>Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74670).</p>	Center for Quality Assessment and Improvement in Mental Health
N/A/368	62v4	Effective Clinical Care	<p>HIV/AIDS: Medical Visit: Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 90 days between each visit.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).</p>	National Committee for Quality Assurance
N/A/369	158v4	Effective Clinical Care	<p>Pregnant Women that had HBsAg Testing: This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).</p>	OptumInsight
0710/370	159v4	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).</p>	Minnesota Community Measurement
0712/371	160v4	Effective Clinical Care	<p>Depression Utilization of the PHQ-9 Tool: Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74673).</p>	Minnesota Community Measurement
N/A/372	82v3	Community/ Population Health	<p>Maternal Depression Screening: The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74674).</p>	National Committee for Quality Assurance
N/A/373	65v5	Effective Clinical Care	<p>Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74675).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/374	50v4	Communication and Care Coordination	<p>Closing the Referral Loop: Receipt of Specialist Report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).</p>	Centers for Medicare & Medicaid Services/Mathematica
N/A/375	66v4	Person and Caregiver-Centered Experience and Outcomes	<p>Functional Status Assessment for Knee Replacement: Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/376	56v4	Person and Caregiver-Centered Experience and Outcomes	<p>Functional Status Assessment for Hip Replacement: Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/377	90v4	Person and Caregiver-Centered Experience and Outcomes	<p>Functional Status Assessment for Complex Chronic Conditions: Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74678).</p>	Centers for Medicare & Medicaid Services/Mathematica
N/A/378	75v4	Community/Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74678).</p>	Centers for Medicare & Medicaid Services/Mathematica
N/A/379	74v5	Effective Clinical Care	<p>Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74679).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/380	179v4	Patient Safety	<p>ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range: Average percentage of time in which patients aged 18 and older with atrial fibrillation who are on chronic warfarin therapy have International Normalized Ratio (INR) test results within the therapeutic range (i.e., TTR) during the measurement period.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74679).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/381	77v4	Effective Clinical Care	<p>HIV/AIDS: RNA Control for Patients with HIV: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74681).</p>	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
1365/382	177v4	Patient Safety	<p>Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.</p> <p>This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS</p>	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
			Final Rule (see Table 52 at 78 FR 74681).	Improvement
1879/383	N/A	Patient Safety	<p>Adherence to Antipsychotic Medications for Individuals with Schizophrenia: Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).</p>	Health Services Advisory Group/ Centers for Medicare & Medicaid Services
N/A/384	N/A	Effective Clinical Care	<p>Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery: Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).</p>	American Academy of Ophthalmology
N/A/385	N/A	Effective Clinical Care	<p>Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery: Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).</p>	American Academy of Ophthalmology
N/A/386	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).</p>	American Academy of Neurology
N/A/387	N/A	Effective Clinical Care	<p>Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users: Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/388	N/A	Patient Safety	<p>Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy): Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).</p>	American Academy of Ophthalmology/American College of Healthcare Sciences
N/A/389	N/A	Effective Clinical Care	<p>Cataract Surgery: Difference Between Planned and Final Refraction: Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67810).</p>	American Academy of Ophthalmology/American College of Healthcare Sciences

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
N/A/390	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67810).</p>	American Medical Association-Physician Consortium for Performance Improvement/American Gastroenterological Association
0576/391	N/A	Communication and Care Coordination	<p>Follow-Up After Hospitalization for Mental Illness (FUH): The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported:</p> <ul style="list-style-type: none"> - The percentage of discharges for which the patient received follow-up within 30 days of discharge - The percentage of discharges for which the patient received follow-up within 7 days of discharge. <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67811).</p>	National Committee for Quality Assurance
2474/392	N/A	Patient Safety	<p>HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation: Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation</p> <p>This measure is reported as four rates stratified by age and gender:</p> <ul style="list-style-type: none"> • Reporting Age Criteria 1: Females less than 65 years of age • Reporting Age Criteria 2: Males less than 65 years of age • Reporting Age Criteria 3: Females 65 years of age and older • Reporting Age Criteria 4: Males 65 years of age and older <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).</p>	The Heart Rhythm Society
N/A/393	N/A	Patient Safety	<p>HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision: Infection rate following CIED device implantation, replacement, or revision.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).</p>	The Heart Rhythm Society
1407/394	N/A	Community/Population Health	<p>Immunizations for Adolescents: The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).</p>	National Committee for Quality Assurance
N/A/395	N/A	Communication and Care Coordination	<p>Lung Cancer Reporting (Biopsy/Cytology Specimens): Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).</p>	College of American Pathologists
N/A/396	N/A	Communication and Care Coordination	<p>Lung Cancer Reporting (Resection Specimens): Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).</p>	College of American Pathologists

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [†]	Measure Steward
N/A/397	N/A	Communication and Care Coordination	<p>Melanoma Reporting: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).</p>	College of American Pathologists
N/A/398	N/A	Effective Clinical Care	<p>Optimal Asthma Control: Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).</p>	Minnesota Community Measurement
2452/399	N/A	Effective Clinical Care	<p>Post-Procedural Optimal Medical Therapy Composite (Percutaneous Coronary Intervention): Percentage of patients aged 18 years and older for whom PCI is performed who are prescribed optimal medical therapy at discharge.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).</p>	American College of Cardiology/American Heart Association/American Medical Association-Physician Consortium for Performance Improvement
N/A/400	N/A	Effective Clinical Care	<p>One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk: Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67814).</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/401	N/A	Effective Clinical Care	<p>Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67814).</p>	American Medical Association-Physician Consortium for Performance Improvement/American Gastroenterological Association
N/A/402	N/A	Community/Population Health	<p>Tobacco Use and Help with Quitting Among Adolescents: The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.</p> <p>This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67815).</p>	National Committee for Quality Assurance/National Collaborative for Innovation in Quality Measurement
N/A/403 ‡	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>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 or peritoneal dialysis who are referred to hospice care.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Renal Physicians Association/American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/439 ‡	N/A	Efficiency and Cost Reduction	<p>Age Appropriate Screening Colonoscopy: The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
N/A/404 ‡	N/A	Effective Clinical Care	<p>Anesthesiology Smoking Abstinence: The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Society of Anesthesiologists
N/A/421 ‡	N/A	Effective Clinical Care	<p>Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal: Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society of Interventional Radiology
N/A/405 ‡	N/A	Effective Clinical Care	<p>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:</p> <ul style="list-style-type: none"> •Liver lesion ≤ 0.5 cm •Cystic kidney lesion < 1.0 cm •Adrenal lesion ≤ 1.0 cm <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Radiology
N/A/406 ‡	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Radiology
N/A/407 ‡	N/A	Effective Clinical Care	<p>Appropriate Treatment of MSSA Bacteremia: Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Infectious Disease Society of America
N/A/408 ‡	N/A	Effective Clinical Care	<p>Opioid Therapy Follow-up Evaluation: All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
N/A/409 ‡	N/A	Effective Clinical Care	<p>Clinical Outcome Post Endovascular Stroke Treatment: Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society of Interventional Radiology
0711/411 ‡	N/A	Communication and Care Coordination	<p>Depression Remission at Six Months: Adult patients age 18 years 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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Minnesota Community Measurement
N/A/412 ‡	N/A	Effective Clinical Care	<p>Documentation of Signed Opioid Treatment Agreement: All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Neurology
N/A/413 ‡	N/A	Effective Clinical Care	<p>Door to Puncture Time for Endovascular Stroke Treatment: Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society of Interventional Radiology
N/A/415 ‡	N/A	Efficiency and Cost Reduction	<p>Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older: Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Emergency Physicians
N/A/416 ‡	N/A	Efficiency and Cost Reduction	<p>Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years: Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network prediction rules for traumatic brain injury.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Emergency Physicians
N/A/414 ‡	N/A	Effective Clinical Care	<p>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 Opioid Therapy in the medical record.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Neurology
0053/418 ‡	N/A	Effective Clinical Care	<p>Osteoporosis Management in Women Who Had a Fracture: The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	National Committee for Quality Assurance/ American Medical

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
				Association-Physician Consortium for Performance Improvement
N/A/419 ‡	N/A	Efficiency and Cost Reduction	<p>Overuse Of Neuroimaging For Patients With Primary Headache And A Normal Neurological Examination: Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Neurology
N/A/428 ‡	N/A	Effective Clinical Care	<p>Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence: Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society
N/A/429 ‡	N/A	Patient Safety	<p>Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy: Percentage of patients who are screened for uterine malignancy prior to surgery for pelvic organ prolapse.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society
2063/422 ‡	N/A	Patient Safety	<p>Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury: Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society
0465/423 ‡	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society for Vascular Surgeons
2671/424 ‡	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Society of Anesthesiologists
N/A/425 ‡	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Gastroenterology/ American Gastroenterologic Association/ American Society for Gastrointestinal Endoscopy

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^Y	Measure Steward
N/A/426 ‡	N/A	Communication and Care Coordination	<p>Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU): Percentage of patients, regardless of age, 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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Society of Anesthesiologists
N/A/427 ‡	N/A	Communication and Care Coordination	<p>Post-Anesthetic Transfer of Care: 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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Society of Anesthesiologists
N/A/430 ‡	N/A	Patient Safety	<p>Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy: Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Society of Anesthesiologists
2152/431 ‡	N/A	Community/ Population Health	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Medical Association-Physician Consortium for Performance Improvement
N/A/432 ‡	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society
N/A/433 ‡	N/A	Patient Safety	<p>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 time of index surgery that is recognized intraoperative or within 1 month after surgery.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society
N/A/434 ‡	N/A	Patient Safety	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Urogynecologic Society

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description ^y	Measure Steward
N/A/410 ‡	N/A	Person and Caregiver-Centered Experience and Outcomes	<p>Psoriasis: Clinical Response to Oral Systemic or Biologic Medications: Percentage of psoriasis patients receiving oral 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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Dermatology
N/A/435 ‡	N/A	Effective Clinical Care	<p>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.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American Academy of Neurology
N/A/436 ‡	N/A	Effective Clinical Care	<p>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:</p> <ul style="list-style-type: none"> • Automated exposure control • Adjustment of the mA and/or kV according to patient size • Use of iterative reconstruction technique <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
1523/417 ‡	N/A	Patient Safety	<p>Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive: Percentage of patients undergoing open repair of abdominal aortic aneurysms (AAA) who are discharged alive.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society for Vascular Surgeons
N/A/437 ‡	N/A	Patient Safety	<p>Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure: Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society of Interventional Radiology
N/A/438 ‡	N/A	Effective Clinical Care	<p>Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:</p> <ul style="list-style-type: none"> • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Centers for Medicare & Medicaid Services/ Mathematica/Quality Insights of Pennsylvania

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward
N/A/420 ‡	N/A	Effective Clinical Care	<p>Varicose Vein Treatment with Saphenous Ablation: Outcome Survey: Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.</p> <p>This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.</p>	Society of Interventional Radiology

‡ This measure is new to the Physician Quality Reporting System and has been adopted for reporting beginning in CY 2016.

¥ 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. This column also contains summary of public comments and CMS’s responses, if applicable.

7. Request for Input on the Provisions Included in the Medicare Access and CHIP

Reauthorization Act of 2015 (MACRA)

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10, enacted on April 16, 2015) (MACRA) repealed the Medicare sustainable growth rate (SGR) update formula for payments under the Medicare physician fee schedule, established the Merit-based Incentive Payments System (MIPS) under the physician fee schedule, established incentive payments for participation in certain alternative payment models (APMS), and made other changes affecting Medicare payments to physicians and other eligible professionals. We sought public input on the following provisions of the MACRA in the CY 2016 PFS proposed rule (80 FR 41879 through 41880):

- 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. In the proposed rule, we sought public input on specific provisions related to the MIPS, including (80 FR 41879):

- 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.
- 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.
- Which factors to include, individually or in combination, in determining a low-volume threshold.
- Whether a low-volume threshold similar to ones currently used in other CMS reporting programs would be an appropriate low-volume threshold for the MIPS and the applicability of existing low-volume thresholds used in other CMS reporting programs toward MIPS.
- What activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

b. Alternative Payment Models

Section 101(e) of the 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 certain APMs. The statutory amendments made by this section have payment implications for eligible professionals beginning in 2019. As part of our continued commitment to stakeholder engagement, we broadly sought public comments on the promotion of alternative payment models (APMs) in the proposed rule

(80 FR 41879 through 41880). Specifically, we sought comment on approaches for developing and encouraging APMs and on incentive payments for participation in APMs by eligible professionals. We noted that we would be requesting more detailed information in a forthcoming RFI on the following topics: 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 alternative payment entities; quality measures and EHR use requirements; and the definition of nominal financial risk for eligible alternative payment entities.

In response to our solicitation, we received over 90 insightful and informative public comments suggesting matters to consider in our RFI and for future rulemaking. In addition to seeking public comment through the proposed rule, we published a Request for Information (RFI) on October 1, 2015, (80 FR 59102-59113) available at <https://federalregister.gov/a/2015-24906>, asking for additional public comment on more detailed questions related to both MIPS and APMs. We appreciate the many insights and comments that we received, and look forward to additional comments in response to the RFI. We will consider these public comments in future rulemaking.

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.

In this final rule, we summarize the comments we received based on our proposals for the EHR Incentive Program in the CY 2016 PFS proposed rule (80 FR 41880) and state our final policies based on these proposals and comments. Please note that we received numerous comments related generally to the EHR Incentive Program but not related to our specific proposals for the EHR Incentive Program in the CY 2016 PFS proposed rule. While we may take these comments into consideration when developing proposals in the future, we will not address these comments with specificity here.

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’ website 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 anticipated 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 anticipated 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.

Accordingly, to allow providers to upgrade to 2015 Edition CEHRT before 2018, we proposed in the CY 2016 PFS proposed rule (80 FR 41880) 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 noted that the proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on March 30, 2015 (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 proposed in the CY 2016 PFS proposed rule (80 FR 41880) 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 proposed 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 invited comment on our proposals. We note that ONC finalized the proposal to adopt a 2015 Edition CQM reporting certification (at 45 CFR 170.315(c)(3)) in its 2015 Edition final rule. The certification criterion requires health IT to be certified to report CQMs using the QRDA Category I and III standards. It also includes an optional provision to report CQMs in the "form and manner" that CMS requires for submission. We refer readers to 80 FR 62651 through 62652.

The following is a summary of the comments we received regarding these proposals.

Comment: Commenters were supportive of our proposals to revise the CEHRT definition at §495.4. The commenters stated that if CMS intends to require EHR products to be able to submit this data either directly or via a certified file format, the proposal to require the optional portion of the CQM reporting criterion for the CEHRT definition is necessary.

Response: We appreciate the commenters' support for our proposals. Based on the comments received and for the reasons stated previously, we are finalizing these proposals made in the CY 2016 PFS proposed rule, as proposed. We are revising the regulation text under §495.4 to reflect this final policy.

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 9 electronically specified CQMs across 2 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.

In the CY 2016 PFS proposed rule (80 9 FR 41881), we proposed 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 3 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 finalized in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62888), EPs in any year of participation may electronically report clinical quality measures for a reporting period in 2016. Therefore, we proposed that for CY 2016, EPs who are part of a 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 noted 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 invited public comment on these proposals.

We received several comments in response to the proposed group reporting option for CPC practice sites for CY 2016.

Comment: Several commenters supported the alignment between CPC and the Medicare

EHR Incentive Program. They also supported the inclusion of EPs who are in their first year of participation in the Medicare EHR Incentive Program in the proposal to meet the CQM reporting requirement of the Medicare EHR Incentive Program through successful reporting to CPC.

However, a few commenters expressed concern about penalizing first year EPs who submit 12 months of data rather than 90 days.

Response: We appreciate the support for this proposal. To clarify, we proposed that EPs who are part of a CPC practice site and are in their first year of demonstrating meaningful use [in CY 2016] may report CQMs through the CPC group reporting option for CY 2016, and if submitted successfully in accordance with the requirements established by the CPC Initiative and using CEHRT, their CPC reporting would satisfy the CQM requirement for the Medicare EHR Incentive Program. First-year EPs who successfully report CQMs through the CPC group reporting option for the CY 2016 reporting period and meet all other requirements for the Medicare EHR Incentive Program would avoid the meaningful use payment adjustment under Medicare in CY 2018. We note that in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62905), we established that in CY 2016, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2016, and an EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by October 1, 2016. Therefore, to avoid the meaningful use payment adjustment under Medicare in CY 2017, EPs who are demonstrating meaningful use for the first time in CY 2016 and report CQMs through the CPC group reporting option must also successfully report CQMs by attestation through the EHR Incentive Program's Registration and

Attestation System for a 90-day reporting period in CY 2016 by October 1, 2016, or apply for a significant hardship exception from the CY 2017 payment adjustment.

Comment: One commenter expressed concern that CPC practice site vendors may not be able to support the CPC CQM reporting requirements.

Response: We understand that some practices found it challenging to meet the CPC CQM reporting requirements due to issues involving their vendors. However, the CPC CQM results from program year 2014 demonstrated that a substantial majority of the CPC practices were able to meet the CPC requirements.

Comment: Two commenters suggested that electronic quality measurement should look across longer periods of time, utilize more data sources, and consider care in settings other than hospitals and ambulatory care such as long-term post-acute care, behavioral health and palliative care.

Response: The Medicare EHR Incentive Program is limited by statute to eligible professionals, eligible hospitals, and critical access hospitals. There are separate CMS programs, however, that require quality reporting from other types of providers. In addition, certain measures in the Medicare EHR Incentive Program include information about care from other settings or for particular conditions, such as behavioral health, and we hope to continue to add measures for a wider range of specialties and settings with a focus on outcomes measures.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the proposals for the group reporting option for CPC practice sites for CY 2016 as proposed.

K. Discussion and Acknowledgement of Public Comments Received on the Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

1. Background

We have been working to develop and test models of advanced primary care under the authority of section 1115A of the Act. Through these models, we plan to evaluate whether advanced primary care results in higher quality and more coordinated care at a lower cost to Medicare. We are currently testing the Comprehensive Primary Care (CPC) initiative.

In the CPC initiative, we are collaborating with commercial payers and state Medicaid agencies to test a payment and service delivery model that includes the payment of monthly non-visit based per beneficiary per month care management fees and shared savings opportunities. The 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 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 primary care practitioner 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. More information on the CPC initiative can be found on the CMS Center for Medicare and Medicaid Innovation’s Web site at

<http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/>.

In the CY 2016 PFS proposed rule (80 FR 41881 through 41884), we presented a description of the CPC initiative and solicited public comments regarding policy and operational issues related to a potential future expansion of the CPC initiative. Section 1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the CPC initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the 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. The decision of whether or not to expand 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. Given that further evaluation is needed to determine its impact on both Medicare cost and quality of care, we did not propose an expansion of the CPC initiative in the CY 2016 PFS proposed rule.

Consistent with our continuing commitment to engaging stakeholders in CMS's work, we solicited public comments on a variety of issues to broaden and deepen our understanding of the important issues and challenges regarding primary care payment and transformation in the health care marketplace. Among other subject-matter areas, we solicited public comments on practice readiness, practice standards and reporting, practice groupings, interaction with state primary care transformation initiatives, learning activities, payer and self-insured employer readiness, Medicaid, quality reporting, interaction with the chronic care management code, and provision of data feedback to practices. In response to our solicitation, we received over 90 timely and informative public comments suggesting matters to consider in a potential future expansion of the CPC initiative, including engagement of electronic health record vendors, coaching on leadership and change management, documentation, beneficiary cost-sharing, care management, further testing of the CPC initiative, eligibility for incentive payments for participation in Alternative Payment Models under MACRA, auditing requirements, aggregation of payer and clinical data, and engagement with providers across the broader medical neighborhood. These comments, submitted by a variety of stakeholders, broadly supported CPC expansion. We appreciate the commenters' views and recommendations. We will consider the public comments we received if the CPC initiative is expanded in the future through rulemaking.

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 addressed the following policies under the Shared Savings Program in the CY 2016 PFS 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 who bill through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the GPRO web interface.

We identified certain policies related to the quality measures and quality performance standard that we proposed in the CY 2016 PFS proposed rule. Specifically, we proposed 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 billing through the TIN of an ACO participant may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the 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. 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, in the CY 2016 PFS proposed rule we proposed 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 proposed to add a statin therapy 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 45 lists the Shared Savings Program quality measure set, including the one measure we proposed to add, which would be used to assess ACO quality starting in 2016.

- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

We proposed 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 proposed this measure to continue Shared Savings Program alignment with the PQRS program and Million Hearts® Initiative. We proposed that the multiple denominators would 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 solicited public comment on the implementation of the measure for the Shared Savings Program. We solicited comment on whether the measure should be considered a single measure with weighted denominators or three measures given the multiple denominators that 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 solicited 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 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, which could result in a low number of beneficiaries meeting the measure denominators. Hence, we proposed 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 proposed 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 proposed 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 of the proposed rule (80 FR 41886 through 41888). 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 also solicited 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 solicited 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 the 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.

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 44 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 44 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes with the proposed Statin Therapy measure in the Preventive Health domain. Under our proposal, 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 also solicited 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.

TABLE 44: 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%
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%

Comment: Most comments we received supported the addition of the Statin Therapy measure to the Preventative Health domain, but some stakeholders recommended changes to the denominators or suggested expanding treatments beyond statins to include other effective treatments. An example of a suggested change to the measure that we received is a recommendation to modify the denominators to report the percentage of the high risk population that is both on a statin and has achieved an LDL < 100. In addition, numerous commenters urged CMS to seek endorsement of the Statin Therapy measure from the National Quality Forum prior to implementation in the Shared Savings Program. Many commenters supported increasing the beneficiary oversample for reporting the measure, but did not think it would resolve the issue of insufficient beneficiaries meeting the multiple denominators and did not provide alternative suggestions. Most commenters supported scoring the measure as a single measure and retaining the measure as pay-for-reporting for the entire agreement period due to concerns with the measure specifications and lack of NQF endorsement. However, some commenters agreed with our proposal and recommended the measure transition to pay-for-performance after being pay-for-reporting for 2 years.

We also received many comments opposing the addition of the Statin Therapy measure, citing concerns about specifications that are not publicly available and about adding a process measure that has not been tested and still does not conform to the four major statin therapy benefit categories from the 2013 ACC/AHA clinical guidelines. Commenters suggested CMS move toward replacing process measures with health outcome and patient-reported outcome measures.

Response: After reviewing the comments, we are finalizing our proposal for adding the Statin Therapy quality measure to the quality measure set for the Shared Savings Program. As is our standard practice, we intend to make specifications for this measure available prior to the performance year in which it is applicable. We therefore anticipate the final specifications for the Statin Therapy measure will be made public prior to the 2016 performance year. In response to the commenters who expressed concern that this measure requires further testing and may not cover all components of the current clinical guidelines, we note that CMS requires that all measures included in the program undergo feasibility, validity, and reliability testing. CMS tested the measure to assess the technical feasibility of the measure, as well as the extent to which measure scores are valid and reliable. In addition, the measure underwent qualitative testing activities across multiple testing sites to assess the feasibility, face validity and usability of the measure. The testing was conducted in accordance with the processes and principles outlined in CMS's [A Blueprint for the Measures Management System](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html) (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html>). This measure also reflects CMS's effort to adhere to current clinical guidelines. The measure incorporates three of the four components of the 2013 ACC/AHA clinical guidelines, and thus, this initial implementation of

the measure provides an opportunity to fill a key clinical gap in the program. Based on feedback and guidance from the technical expert panel and measure owner, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. Although, we believe the measure conforms to current guidelines, we understand the ACC is convening stakeholders to further discuss and review the guidelines. CMS will continue to monitor and review updates to guidelines and take these into consideration in the future. We appreciate comments suggesting the use of an NQF-endorsed measure. However, there is no similar, feasible, and practical measure that has been endorsed by the NQF and submitted to the Measure Applications Partnership. While some commenters suggested expanding the measure to other effective treatments, current clinical guidelines indicate statin therapy is the appropriate standard of care. We believe that requiring ACOs to report on the Statin Therapy measure is important to encourage focus on important preventive care and effective treatment for a high prevalence condition. Moreover, inclusion of this measure, as outlined previously, will enhance alignment with PQRS and the Million Hearts ® Initiative, and focus on important preventive care and effective treatments for high prevalence conditions.

We are finalizing our proposal of adding the Statin Therapy measure as a single 3-part measure scored as 2 points with an oversample of 750 beneficiaries. We are increasing the oversample from 616 to 750 beneficiaries for this measure, but the consecutive reporting requirement for measures reported through the CMS web interface will remain at 248 beneficiaries. Although we proposed transitioning the measure to pay-for-performance in the third year of the agreement period, we are finalizing the measure as pay-for-reporting for all reporting years because a majority of commenters supported finalizing the measure as pay-for-reporting only and because ACC and other experts are continuing to discuss non-statin therapy

and reducing ASCVD risk. These discussions may, in turn, cause modifications in the measure specifications. For these reasons, we believe 2 years is too short a timeline to transition to pay for performance in accordance with our current rules and therefore will finalize this measure as pay for reporting for all three years. By finalizing the measure as pay-for-reporting in all agreement years we hope to provide ACOs and their ACO participants and ACO providers/suppliers with an opportunity to gain experience and become familiar with the ACC/AHA clinical guidance and multiple denominators of the measure. However, we agree with commenters that stated support for measures of statin therapy and the importance of moving to pay for performance. We therefore intend to revisit this measure in future rulemaking to propose a timeline for phasing in pay for performance. As a result of adding this measure, the total points possible in the Preventive Health domain will increase from 16 points to 18 points and the total measures in the Shared Savings Program measure set reported by ACOs will increase from 33 measures to 34 measures.

TABLE 45: Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase		
						In R – Reporting	P – Performance	
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		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
	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)		Adapted NQF #2510 CMS	Claims	R	R	P
	ACO - 36	All-Cause Unplanned Admissions for Patients with Diabetes		NQF#TBD CMS	Claims	R	R	P
	ACO -37	All-Cause Unplanned Admissions for Patients with Heart Failure		NQF#TBD CMS	Claims	R	R	P
	ACO -38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions		NQF#TBD CMS	Claims	R	R	P
	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	CMS Web Interface	R	P	P	

				NCQA				
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 CMS	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Depression	ACO - 40	Depression Remission at Twelve Months		NQF #0710 MNCM	CMS Web Interface	R	R	R
Clinical Care for At Risk Population - Diabetes	ACO - 27	Diabetes Composite (All or Nothing Scoring): ACO - 27: Diabetes Mellitus: Hemoglobin A1c Poor Control		NQF #0059 NCQA (individual component)	CMS Web Interface	R	P	P
	ACO - 41	ACO - 41: Diabetes: Eye Exam		NQF #0055 NCQA (individual component)	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension (HTN): Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Ischemic Vascular Disease	ACO-30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic		NQF #0068 NCQA	CMS Web Interface	R	P	P
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

c. 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, in the CY 2016 PFS proposed rule (80 FR 41889) we proposed to adopt a general policy under which we would 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. In the proposed rule, we explained that we expected to 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 proposed 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 solicited 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.

Comment: Comments supported the proposed policy not to assess ACO performance on measures that no longer align with clinical guidelines or may cause patient harm; however, many commenters suggested the most appropriate method to handle such measures is immediate suspension and further evaluation of the measure by stakeholders or NQF rather than maintaining the measure as pay-for-reporting.

Response: We are finalizing our proposal to 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 practice due to clinical guideline changes or clinical evidence suggesting that the continued collection of the data may result in harm to patients. We believe that maintaining or reverting a measure to pay-for-reporting will ensure

ACOs will not be scored on their performance on the measure while CMS and the measure steward assess the measure specifications. CMS may propose to retire such a measure in the next rulemaking cycle, which will offer the public an opportunity to comment and will put ACOs on sufficient notice about the retirement of the measure. We appreciate the comments suggesting immediate suspension and will explore this option further and may consider proposing such an approach in the future.

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 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 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” 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. In addition, we also updated the measure specifications to include providers who met meaningful use requirements within the past 2 years to account for the changes in meaningful use requirements and to support the progression of HIT adoption and use.

We continue to believe that measures that 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. In October 2015, final rules were issued for “Stage 3” of the EHR Incentive program (80 FR 62761), as well as the 2015 Edition of ONC certification criteria (80 FR 62601). Together, these rules 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 <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-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. Although we did not propose any

changes to the current measure “Percent of PCPs who Successfully Meet Meaningful Use Requirements” (ACO-11), we solicited comments 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 welcomed 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?

We appreciate the numerous thoughtful comments on the questions we posed regarding the current measure “Percent of PCPs who Successfully Meet Meaningful Use Requirements” (ACO-11) and its evolution as a part of the Shared Savings Program. We will use the feedback as we determine how the measure could be updated and expanded to further incentivize and reward providers for using and adopting more advanced health IT. We would make any modifications necessary to permit the evolution of the measure through future rulemaking.

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 an 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 proposed in the CY 2016 PFS proposed rule (80 FR 41890) 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 indicated that 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.

Comment: We received few comments on this proposal, but all comments supported the proposed changes because the revisions would clarify the reporting requirement and align the policy under the Shared Savings Program with PQRS.

Response: We appreciate the comments in support of our proposal. We agree that the proposed revisions to §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, will clarify the reporting requirement and align the Shared Savings Program policy with PQRS. As a result, we are finalizing our proposed revisions to §425.504.

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 proposed 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 Skilled Nursing Facilities (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 E/M 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 November 2014 proposed rule, in some cases, hospitalists that perform E/M 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 suggested excluding SNF visit codes furnished in POS 31 to potentially relieve physicians practicing exclusively in skilled nursing facilities from the requirement that 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. Although 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, in the CY 2016 PFS proposed rule we proposed 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. Although 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. We indicated in the proposal that if we finalized this proposal, we anticipated 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 then be applicable for all ACOs starting with the 2017 performance year. This approach 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 proposed 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. ACO participant TINs that include only ACO professionals that furnish services exclusively in SNFs would not be required to be exclusive to a single ACO. We also note, however, that an ACO participant TIN that includes both ACO professionals that furnish services exclusively in SNFs as well as other ACO professionals that furnish primary care services in non-SNF settings would continue to be required to be exclusive to a single ACO since such an ACO participant TIN would be submitting claims for primary care services that would continue to be used for beneficiary assignment.

The following is a summary of the comments we received regarding these proposals:

Comment: Nearly all commenters that submitted comments supported the proposal to exclude services billed under CPT codes 99304 through 99318 when the claim includes the POS 31 modifier. These commenters agreed that it would increase the accuracy of the beneficiary assignment methodology. Although beneficiaries' care may be coordinated during their time in a 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 care needs. Hospitalists and other physicians providing services in SNFs also indicated their support for the proposal, agreeing that in some circumstances it could relieve them from the requirement that they must be exclusive to a single ACO if their services are considered in assignment. In addition, a commenter opposed the proposal, believing that the proposal fails to recognize the importance in rural areas of SNFs as a vital site of primary care services. This commenter reported that SNF residents in rural areas often have longer stays for chronic conditions requiring intensive maintenance and coordination efforts. As a result, the commenter believes the proposal would deprive ACO attribution and benefits to a significant portion of the rural "Medicaid" population and those in most need of such patient-centered service delivery. Another commenter questioned the validity of excluding SNF visits from the beneficiary assignment process while including any cost savings generated by ACOs through collaborative affiliation with SNFs.

Response: 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 care needs. Further, based on our preliminary analysis and input from commenters, we do not believe removal of these claims will result in a significant reduction of assigned beneficiaries from an ACO, although we recognize that assignment to some ACOs may be more

affected than others, depending on the practice patterns of their ACO provider/suppliers.

We disagree with the comment that this approach would deprive ACO attribution and benefits to a significant portion of the rural Medicaid population and those in most need of such patient-centered service delivery. While residing in a SNF, patients are primarily receiving continued acute medical care and rehabilitative services. Further, assignment under the Shared Savings Program is only available to Medicare beneficiaries, and the assignment methodology includes primary care services furnished in RHCs. We believe that it is more appropriate for such patients to be assigned to ACOs based on the primary care professionals in the community (including NFs) who are typically responsible for providing care to meet their true primary care needs. We also disagree with the commenter who questioned the validity of excluding the SNF visits from the beneficiary assignment process while including the cost savings generated by an ACO through collaborative affiliation with SNFs. We believe that including such expenditures as part of determining an ACO's shared savings or losses provides an appropriate incentive for ACOs to coordinate and manage a patient's overall care. We also note this is consistent with the statutory requirements in section 1899(c) of the Act, which requires that beneficiaries be assigned to ACOs based on their utilization of primary care services, and requires that ACOs be accountable for the total cost of the beneficiary's care (that is, both part A and B expenditures).

After considering the comments, we are finalizing the proposal to amend paragraph (2) under §425.20 to exclude from our definition of primary care services claims billed under CPT codes 99304 through 99318 when the claim includes the POS code 31 modifier. We believe that excluding these services furnished in SNFs from the definition of primary care services will complement our goal of assigning beneficiaries to an ACO based on their utilization of primary care services. We are also finalizing our proposal to make a conforming change to the definition of primary care services 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, which excludes services furnished in SNFs from the definition of primary care services effective starting with the 2017 performance year. To conform to the precedent set by the June 2015 Shared Savings Program final rule ([80 FR 32758](#)), we will adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for an ACO reflects the use of the same assignment rules as would apply in the performance year.

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 the institutional claim submitted by an ETA hospital 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 website 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 proposed 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 allows us to continue to accurately assign Medicare FFS beneficiaries to ACOs based on their utilization of primary care services furnished by ACO professionals, including those ACOs that may include ETA hospitals.

We would note that 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 proposed 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 proposed 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 proposed 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 approach 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 proposed 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.

The following is a summary of the comments we received regarding these ETA proposals:

Comment: We received very few comments on these ETA proposals; all these comments supported the proposals.

Response: We appreciate the support for our proposals. We continue to believe that including claims for primary care services furnished in ETA hospitals 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.

Accordingly, we are finalizing our proposals to codify our current practice and guidance regarding the treatment of claims for primary care services submitted by ETA hospitals in the assignment process. We are amending 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 to codify our current practice for performance year 2016 and subsequent performance years. We are revising §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 will 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. We are also finalizing our proposal 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. In addition, we are also correcting a typographical error in §425.102(b) by revising “eligible participate” to read “eligible to participate.”

3. Technical Correction

In the 2015 PFS final rule with comment period (79 FR 67931), we finalized corrections to a technical error and a typographical error at §425.502(d)(2)(ii) that were not subsequently reflected in the regulations text. Specifically, we proposed and finalized a technical correction to eliminate the specific reference to paragraph (c) of §425.216. The provision at § 425.216, which addresses the actions we may take prior to termination of an ACO from the Shared Savings Program, does not include paragraph (c). We also finalized a correction to a typographical error in §425.502(d)(2)(ii) by revising “actions describe” to read “actions described.” In the 2015 PFS final rule with comment period, we noted that we did not receive any objections to correcting the typographical error or the other minor technical correction to §425.502(d)(2)(ii), and stated that we intended to finalize them as proposed (79 FR 67931). However, we inadvertently neglected to include these corrections in the regulations text section of the 2015 PFS final rule. As a result of this oversight, the CFR was not updated to reflect our final policies. At this time, therefore,

we are correcting the oversight by including the previously finalized revisions to §425.502(d)(2)(ii) in this final rule as they were finalized in the 2015 PFS final rule with comment period.

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 and Physician Feedback program continue CMS' initiative to recognize and reward providers based on the quality and cost of care provided to their patients, increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.

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.

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 Final Rule with Comment Period

As a general summary, in the CY 2016 PFS proposed rule (80 FR 41892 through 41908) we proposed 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 to 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 methodology 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 CY 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 CY 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 solicited comment on, but made 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). Our previously-finalized policy is that, 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 and solo practitioners, respectively, are removed from the

PECOS-generated list if during the performance period for the applicable CY payment adjustment period, based on our analysis of claims, the group did not have the required number of EPs that submitted claims or the solo practitioner did not submit claims. 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 through 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 through 67941 and 67951 through 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 proposed 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 proposed to update §414.1210(c) accordingly.

The following is a summary of the comments we received on these proposals.

Comment: Several commenters supported our proposal to determine a TIN's size 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, recognizing that the result would be that the group would be subject to the lower amount at risk and also lower possible upward payment adjustment.

Response: We appreciate these commenters' support.

Comment: We received a comment suggesting that we consider alternative ways to define "group", other than using a single TIN, and allow options for groups to define themselves and use both TIN and NPI as unique identifiers.

Response: In the CY 2013 PFS final rule with comment period (77 FR 69309), we discussed our rationale for identifying a group for purposes of the VM by its Medicare-enrolled

TIN. We stated that using TINs makes it possible for us to take advantage of infrastructure and methodologies already developed for PQRS group-level reporting and evaluation and affords us flexibility and statistical stability for monitoring and evaluating quality and outcomes for beneficiaries assigned to the group for quality reporting purposes. As discussed in section III.M.4.h. of this final rule with comment period, CY 2018 will be the final payment adjustment period under the VM; therefore, we do not believe it would be appropriate for us to consider revising how we identify groups during the last year of program. We may take these comments under consideration as we develop policies for the Merit-based Incentive Payment System (MIPS) through future notice and comment rulemaking.

Final Policy: After considering the comments received, we are finalizing our proposal 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 the number of EPs indicated by our analysis of the claims data for purposes of determining the payment adjustment amount under the VM. We are also finalizing the proposed updates to §414.1210(c) without modification.

In section III.M.4.b. of the proposed rule (80 FR 41895), we proposed 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 the proposed rule (80 FR 41901-41903), we proposed to apply different payment adjustment amounts under the CY 2018 VM based on the composition of a group. Specifically, in that section, we proposed that the PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs (that is, 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 proposed 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 noted 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 proposed 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. We provided the following examples to illustrate our 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 in section III.M.4.f. of the 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 still 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 in section III.M.4.f. of the 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 welcomed public comment on these proposals. We proposed to revise §414.1210(c) accordingly. The following is a summary of the comments we received on these proposals.

Comment: One commenter supported our proposal to not apply the VM in CY 2018 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, while another commenter indicated that the VM should apply to all groups and solo practitioners regardless of whether or not the groups and solo practitioners consist only of nonphysician EPs.

Response: In section III.M.4.b. of this final rule with comment period, we are finalizing that we will 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, and not to other types of nonphysician EPs who bill under a group's TIN or who are solo practitioners. Therefore, we do not believe it would be consistent with this final policy to apply the VM 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. As noted in the proposed rule, 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.

Final Policy: After considering the comments received, we are finalizing our proposal for the CY 2018 payment adjustment period 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. Under the policy finalized in section III.M.4.b. of this final rule with comment period, the CY 2018 VM will 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 are also finalizing that the VM will 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. We are also finalizing the proposed revisions to §414.1210(c) without modification.

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. Also in that prior rule, we finalized that 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, 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 and that 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, in the CY 2015 PFS final rule with comment period, 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.

Subsequent to our having finalized the preceding policies in the CY 2015 PFS final rule with comment period, the MACRA was enacted on April 16, 2015. Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the 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. 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 because payment adjustments under the MIPS would not apply to them until 2021. Therefore, we proposed (80 FR 41895) 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 proposed to revise §414.1210(a)(4) to reflect this proposed policy. We proposed 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 proposed 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 noted 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 did not propose to revise these policies; however, we noted 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 would add regulation text under §414.1270 to reflect this policy when we established the policies for the VM for the CY 2018 payment adjustment period in future rulemaking. Accordingly, we proposed (80 FR 41895) 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 final rule with comment period, 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 proposed to apply the VM in CY 2018 only to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

The following is a summary of the comments we received on these proposals.

Comment: Many commenters supported our proposal and agreed that 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. Several commenters noted the proposal allows a more coordinated transition from the VM to the MIPS in CY 2019 by extending the VM only to the nonphysician EPs who will be transitioned into the MIPS directly and ensuring that the remaining nonphysician EPs are transitioned to a value-based payment program only once (that is, in 2021 under the MIPS).

Few commenters opposed our proposal and stated that CMS is not required by the statute to apply the VM to nonphysician EPs; nonphysician practices typically have fewer resources than physician practices and struggle to meet reporting requirements; and that subjecting the nonphysician EPs to the VM for only one year is not a valuable use of their practice time and

resources since they will need to learn about the MIPS requirements for CY 2019. Two commenters urged CMS to exclude all nonphysician EPs from the VM in CY 2018.

Response: We appreciate the comments that supported our proposal 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 believe that it would be appropriate to apply the VM to PAs, NPs, CNSs, and CRNAs in CY 2018, and not to other nonphysician EPs, because PAs, NPs, CNSs, and CRNAs are the only nonphysician EPs the MIPS will apply to in CY 2019 and CY 2020. With regard to commenters' concerns about nonphysician EPs, we note that nonphysician EPs are subject to the reporting requirements under the PQRS and must meet the criteria to avoid the PQRS payment adjustment in CY 2018, as discussed in section III.I. of this final rule with comment period. We are finalizing the two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners (as discussed in section III.M.4.c. of this final rule with comment period). We will also hold harmless PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners from downward adjustments under the quality-tiering methodology in CY 2018 (as discussed in section III.M.4.b. of this final rule with comment period). We believe that application of the VM to PAs, NPs, CNSs, and CRNAs in CY 2018 would provide them with incentives to provide high quality and low cost care similar to the incentives offered to physicians under the VM. Consequently, we do not agree with the comments that stated that the VM should not apply to nonphysician EPs in CY 2018.

Comment: A few commenters asked for clarification of the impact of not applying the CY 2018 VM to nonphysician EPs who are not PAs, NPs, CNSs, and CRNAs.

Response: If the VM were not applied to these nonphysician EPs, they would not be

subject to any adjustment (upward, downward, or neutral) under the VM in CY 2018. However, these nonphysician EPs are still subject to the reporting requirements under the PQRS. We encourage these EPs to actively participate in the PQRS and become familiar with the criteria they must meet to avoid the PQRS payment adjustment in CY 2018, as discussed in section III.I. of this final rule with comment period. We also encourage these nonphysician EPs to review our future rulemaking for the MIPS in anticipation of the application of the MIPS to them.

Comment: One commenter stated that since quality and cost benchmarks for NPs must be specific to a NP's specialty, we should adopt meaningful specialty designations for NPs.

Response: The quality and cost benchmarks are based on the national mean and are not specialty-specific. Specifically, we finalized in the CY 2013 PFS final rule with comment period (77 FR 69322) that the benchmark for each quality measure would be the national mean of each measure's performance rate during the year prior to the performance year and that the benchmark for each cost measure is the national mean of each measure's performance rate during the performance year. As related to PQRS measures, because we are allowing flexibility on the quality measures that groups and solo practitioners can report, we believe the most appropriate peer group consists of other groups and solo practitioners reporting the same measure regardless of specialty. We note that we finalized in the CY 2014 PFS final rule with comment period (78 FR 74784) that we will use the specialty adjustment methodology to calculate the expected cost for each cost measure, beginning with the CY 2016 VM. This methodology takes into account the differential costs of specialties in making cost comparisons, and the cost measures are also risk adjusted to account for differences in patient characteristics not directly related to patient care, but that may increase or decrease the costs of care.

We appreciate the concerns raised by the commenter and encourage the commenter to review the procedures for obtaining a CMS specialty code, which are available at

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html>. As noted above, CY 2018 is the final payment adjustment period for the VM. Policies for application of the MIPS to nonphysician EPs in subsequent years would be finalized through future notice and comment rulemaking.

Comment: Several commenters supported our policy to hold groups that consist of nonphysician EPs and solo practitioners who are nonphysician EPs harmless from downward adjustments under the quality-tiering methodology in CY 2018.

Response: We appreciate the comments supporting the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67937) to hold groups and solo practitioners consisting of nonphysician EPs harmless from downward adjustment under the quality-tiering methodology in CY 2018. Because we are finalizing that the VM will apply in CY 2018 only to those nonphysician EPs who are PAs, NPs, CNSs, and CRNAs, we are also finalizing our proposed addition of §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 final rule with comment period, we discuss the final 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.

Final Policy: After considering the comments received, we are finalizing our proposal 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 are finalizing the proposed revisions to §414.1210(a)(4) to reflect this policy without modification. Under this policy, we will apply the VM in CY 2018 to the items and services billed under the PFS by all of the physicians, PAs, NPs, CNSs, and CRNAs

who bill under a group's TIN based on the TIN's performance during the applicable performance period, which we are finalizing as CY 2016 in section III.M.4.h. of this final rule with comment period. The CY 2018 VM will 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.

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. Because the CY 2018 VM will apply only to certain types of nonphysician EPs, all of the PAs, NPs, CNSs, and CRNAs who bill under a group's TIN will be subject to the same VM adjustment that will apply to the physicians who bill under that TIN in CY 2018, and physicians, PAs, NPs, CNSs, and CRNAs billing under the same TIN will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, PAs, NPs, CNSs, and CRNAs 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 also finalizing our proposal 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 are codifying these definitions under §414.1205 without modification. We are also codifying in §414.1270(d) without modification 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.

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 proposed (80 FR 41896) 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 proposed 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 the proposed rule. We also proposed 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 shown in Table 20 of the proposed rule. We proposed 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 proposed 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 of the proposed rule, it was unclear whether CMS systems could support this type of assessment as soon as the CY 2017 VM, and thus our proposal was contingent upon operational feasibility. For the CY 2017 VM, we proposed 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 proposed 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 proposed 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. We proposed that, if our systems were not able to accomplish this, then we would 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 proposed to include in Category 1 for the CY 2018 VM those solo practitioners that meet the criteria, in Table 20 of the proposed rule, to avoid the CY 2018 PQRS payment adjustment as individuals,

We proposed that Category 2 would include those groups and solo practitioners that are subject to the CY 2018 VM and did not fall within Category 1. As discussed in section III.M.4.f.

of this final rule with comment period, we proposed 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 final rule with comment period, we proposed to apply the VM in CY 2018 to the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

We proposed that 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 the proposed rule, we proposed to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. We solicited comment on these proposals.

The following is a summary of the comments we received on these proposals.

Comment: One commenter stated that despite being based on PQRS data, the VM and PQRS programs would continue to have their own sets of regulations, payment adjustments, feedback reports, and deadlines, which result in administrative complexity and redundancy across federal quality programs.

Response: As we stated in the CY 2014 PFS final rule with comment period (78 FR 74767), one of the principles governing our implementation of the VM is to align program requirements to the extent possible. Thus, our proposals for the CY 2018 payment adjustment period for the VM sought to continue to align the VM with the PQRS program requirements and

reporting mechanisms to ensure individual EPs and groups report data on quality measures that reflect their practice. However, the VM and PQRS were created under different statutory authorities and thus must have their own regulations and policies.

As discussed above, under section 101 of the MACRA, CY 2018 will be the final year of the separate PQRS and VM payment adjustments, and the MIPS will apply to payments for items and services furnished on or after January 1, 2019. We believe the creation of the MIPS may help alleviate the concerns raised in the comment, and we encourage the commenter to review our future rulemaking for the MIPS.

Comment: Many commenters supported our proposal to continue to use a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. Commenters also supported our proposals to consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO, in determining whether a group would be included in Category 1 for the CY 2017 and CY 2018 VM.

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

Final Policy: We are finalizing all of the policies as proposed. We are finalizing the two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For purposes of the CY 2018 VM, Category 1 will 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 finalized in Table 28 of this final rule with comment period. We are also finalizing 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 finalized in Table 27 of this final rule with comment period. Under our final policies for the CY 2018 VM, in determining whether a group will be included in Category 1, we will consider whether the 50

percent threshold has been met regardless of whether the group registers for a PQRS GPRO. As noted in the proposed rule, we believe this policy will allow groups that register for a PQRS GPRO but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for purposes of applying the CY 2018 VM. Please note that if a group registers for a PQRS GPRO and meets the criteria to avoid the PQRS payment adjustment as a group, then the group-level quality data reported through the GPRO reporting mechanism would be taken into account for purposes of applying the CY 2018 VM. Lastly, we are finalizing 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 finalized in Table 27 of this final rule with comment period. Category 2 will include those groups and solo practitioners that are subject to the CY 2018 VM and do not fall within Category 1. We are finalizing the corresponding regulation text at §414.1270(d)(1) that reflect these policies without modification.

For a group or solo practitioner 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) must be met during the reporting periods occurring in CY 2016 for the CY 2018 PQRS payment adjustment. As finalized in section III.M.4.h. of this final rule with comment period, CY 2016 will be the performance period for the VM adjustments that will apply during CY 2018. In section III.M.4.f. of this final rule with comment period, we discuss the CY 2018 payment adjustment amounts for groups and solo practitioners that fall in Category 1 and Category 2 for the CY 2018 VM.

We are also finalizing our proposal to revise the criteria for groups to be included in Category 1 for the CY 2017 VM. We determined that it is operationally feasible for our system

to utilize data reported through a mechanism other than the one through which a group registered to report under PQRS GPRO. Therefore, for the CY 2017 VM, we are finalizing that Category 1 will include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as a group practice participating in the PQRS GPRO in CY 2015. Category 1 will also include groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals. Under our final policies for the CY 2017 VM, in determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO in CY 2015. We believe this policy will allow groups that register for a PQRS GPRO, but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for purposes of applying the CY 2017 VM. Please note that if a group registers for a PQRS GPRO and meets the criteria to avoid the PQRS payment adjustment as a group, then the quality data reported by the group would be taken into account for purposes of applying the CY 2017 VM. We are revising §414.1270(c)(1)(i) to reflect this change in policy for the CY 2017 VM.

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. That is, 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 final rule with comment period, 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 proposed to continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We proposed 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 comment 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 proposed to revise §414.1270 to reflect these proposals. We solicited comments on these proposals. In section III.M.4.f. of this final rule with comment period, we discuss the 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 stated our belief in the proposed rule that 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 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 final rule with comment period, 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. As we stated that we intended to do, in September of 2015, we made annual QRURs, based on CY 2014 data, available to all groups and solo practitioners. The reports show TINs their performance during CY 2014 on all of the quality and cost measures that were used to calculate the CY 2016 VM. Thus, we believe groups with between 2 to 9 EPs and physician solo practitioners will have had 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 received 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 expressed our belief that it would be 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 stated that we would 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.

The following is a summary of the comments we received on these proposals.

Comment: Some commenters supported our proposal to apply the quality-tiering methodology to all groups and solo practitioners that are in Category 1 for the CY 2018 VM. However, other commenters were opposed to the application of the quality-tiering methodology in general. Many commenters had concerns about our proposal to apply the downward adjustment to groups with between 2 to 9 EPs and physician solo practitioners under the quality-tiering methodology in CY 2018 and urged CMS to continue to hold these groups and solo practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. Commenters noted methodological concerns (that is, potential small sample size, lack of specialist-specific measures, and episode-based cost measures); perceived lack of awareness of or resources to interpret the QRURs; and need to become familiar with the MIPS requirements after only one year of being subject to downward adjustments under the quality-tiering methodology under the VM.

Response: We appreciate the commenters' support for our proposal to apply upward and downward adjustments under quality-tiering for groups of two to nine EPs consisting of at least one physician and to physician solo practitioners. We disagree that we should not apply downward adjustments under the quality-tiering methodology to physician groups with between 2 to 9 EPs and physician solo practitioners. We believe that applying full quality-tiering to these groups and solo practitioners, coupled with the lower adjustment rates and changes to improve measure reliability, continues momentum to prepare smaller groups and solo practitioners for value-based payment including a smoother transition to the MIPS.

For the comments concerning small sample size, we note that in recent analyses based on the measure specifications used for the 2016 VM and the proposed case sizes for the 2017 VM, average reliabilities for TINs with less than 10 EPs for all claims-based measures, except the all-cause hospital readmissions measure and the Medicare Spending per Beneficiary (MSPB)

measure, exceeded the threshold for moderate reliability (that is, 0.4). The average reliability for the all-cause hospital readmissions measure and MSPB measure were near the threshold for moderate reliability. We were, however, persuaded by commenters' concerns to perform a reliability analysis at a more granular level than the analyses we had previously conducted. We utilized the most recently available performance data, CY 2014, for this analysis, and we looked not only at groups of fewer than ten EPs, but also further broke down the data into a reliability analysis for solo practitioners, groups of two to five EPs, and groups of fewer than ten EPs. The results of this analysis are displayed in Table 46.

TABLE 46: Average Reliability of Claims-Based Measures Used for the 2016 VM Payment Adjustment, by TIN size

Measure	Minimum Case Size	1 EP	2-5 EPs	Fewer than 10 EPs	10 or more EPs
ACSC Acute Composite	20	0.64	0.72	0.67	0.78
ACSC Chronic Composite	20	0.67	0.71	0.68	0.79
All-Cause Hospital Readmissions	200	0.34*	0.37*	0.37*	0.56
Per Capita Costs for All Attributed Beneficiaries	20	0.74	0.71	0.73	0.80
Medicare Spending per Beneficiary	125	0.40	0.48	0.48	0.67
Medicare Spending per Beneficiary	100	0.37	0.44	0.45	0.64

Note: All measures were computed based on 2014 data using measure specifications for the 2016 Value Modifier.

Our new analysis reveals that, in order for solo practitioners and groups with two to five EPs to meet the average reliability threshold of 0.4 that we discussed in the CY 2013 PFS rulemaking (77 FR 45009, 69322), a minimum number of 125 episodes is required for the MSPB measure, and even at 200 cases, the reliability of the all-cause hospital readmission measure does not meet our threshold for these solo practitioners and small groups. Because these measures do not meet the threshold for what we consider to be moderate reliability for solo practitioners and groups of two to five EPs, we are finalizing our proposed policy to apply upward, neutral, and downward adjustments under quality-tiering in CY 2018 to all physician solo practitioners and groups of physicians, with modifications to address reliability concerns for smaller groups and

solo practitioners. For the CY 2017 and CY 2018 payment adjustment periods, we will increase the minimum number of episodes required for inclusion of the MSPB measure in the cost composite of the VM to 125 episodes (discussed in section III.M.4.k. of this final rule), and we will not include the all-cause hospital readmission measure in the calculation of the quality composite of the VM for solo practitioners or groups of two to nine EPs. For 2018 VM payment adjustments, the policies to increase the minimum number of episodes required for inclusion of the MSPB measure to 125 episodes and to remove the all-cause hospital readmission measure in the calculation of the 2018 VM will also apply for nonphysician EPs who are solo practitioners and groups consisting of nonphysician EPs. We continue to believe it is important to apply upward, neutral, or downward adjustments under quality-tiering to these solo practitioners and groups of EPs, in order to maintain the momentum of improving quality and to continue to emphasize the importance of quality and cost performance under the VM and the upcoming MIPS.

With regard to comments that there are an insufficient number of specialist-specific measures, we do not believe that this would disadvantage smaller groups or solo practitioners. We note that our current policies for the VM, as well as our proposals for the CY 2018 payment adjustment period, include all available PQRS reporting mechanisms, including registries that may be specialty-focused. We also note that the VM methodology includes additional safeguards to guard against misclassification—we finalized in the CY 2013 PFS final rule with comment period (77 FR 69325) the adoption of the quality-tiering model where we classify quality composite scores and cost composite scores each into high, average, and low categories based on whether these scores are at least one standard deviation from the mean and are also statistically significantly different from the mean at the 5.0 percent level of significance, in order to apply the VM upward or downward adjustment only when a group's performance is

significantly different from the national mean. The result of this focus on outliers is that quality-tiering leads to a small percentage of TINs receiving downward adjustments based on performance— for the 2015 VM, out of the 106 groups that elected quality-tiering and had sufficient data, 11 groups (10.4 percent) received a downward VM adjustment and 14 groups (13.2 percent) received an upward VM adjustment based on performance. Cost measures are also risk-adjusted (77 FR 69318) and specialty-adjusted (78 FR 74784) to account for patient characteristics and specialty-composition of the group, respectively.

As discussed in section III.M.4.m. of this final rule with comment period, we are finalizing the policies that, beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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. This policy is consistent with the policy we previously finalized in the CY 2015 PFS final rule with comment period (79 FR 67934) that, beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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.

With regard to commenters' concern about lack of episode-based cost measures, we believe that the total per capita cost measure, condition-specific total per capita cost measures, and MSPB measure provide sufficient cost performance data for VM cost composite calculation and are inclusive of episode cost-based measures.

In the proposed rule (80 FR 41896-41897), we stated that we believe it is appropriate to

apply both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2018 VM to these groups and solo practitioners and also stated the reasons for our belief. We noted that the proposal 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 is consistent with gradual implementation of the VM, wherein groups with between 10 to 99 EPs (79 FR 67941) and groups with 100 or more EPs (78 FR 74769-74770), consecutively were subject to both upward and downward adjustments under quality-tiering during the second year that the VM applied to them. As discussed in section III.M.4.f. of this final rule with comment period, we are finalizing a policy to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to -2.0 percent for groups with between 2 to 9 EPs and physician solo practitioners. We expect this level of payment at risk to not have a significant financial impact on small groups and solo practitioners in CY 2018 and is consistent with our approach to gradually phase in the VM over time and increase the amount at risk.

With regard to the commenters' suggestion that smaller groups lack awareness of the VM program, we believe that they have been given sufficient time and data with which to become familiar with the program. In September 2015, we made available QRURs based on CY 2014 data to all groups and 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 2016 payment adjustment period. As discussed in section III.M.5.a. of this final rule with comment period, 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 spring of 2016, we intend to disseminate the 2015 Mid-Year QRURs to all groups and solo practitioners. 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. We strongly encourage EPs subject to the VM to proactively educate themselves about the VM program and QRURs by visiting the VM/QRUR website <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html>. The VM/QRUR website contains information on the VM policies for each payment adjustment period, including a link to the 2014 QRURs website that contains detailed information on the methodology used to calculate the CY 2016 VM shown in the CY 2014 QRURs and how to use the information contained in the QRURs.

We note that we work with medical and specialty associations and have National Provider Calls throughout the year to educate physicians and other professionals about the VM program and the QRURs. Further outreach also will be undertaken by our Quality Improvement Organizations (QIOs), which will provide technical assistance to physicians and groups of physicians in an effort to help them improve quality and consequently, performance under the VM program.

Final Policy: After considering the comments received, we are finalizing that we will apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the CY 2018 VM. We are also finalizing our proposal that groups and solo practitioners will be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology (with the exception discussed in section III.M.4.b. of this final rule with comment

period, 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), with the following modifications: We are finalizing an increase to the minimum episode number requirement for the MSPB measure in the CY 2017 and 2018 payment adjustment periods to 125 episodes, for solo practitioners and for groups of all sizes, in section III.M.4.k of this final rule with comment period. In that section, we discuss our proposal in the CY 2016 Medicare PFS proposed rule, to raise the episode minimum for inclusion of this measure in the cost composite to 100 episodes (80 FR 41906) and our final policy to raise the minimum number of episodes to 125. We are also finalizing that we will not include the all-cause hospital readmissions measure in the quality composite for solo practitioners and groups of two to nine EPs for the CY 2017 and 2018 payment adjustment periods. We believe that this final policy best addresses commenters' concerns with small sample sizes for solo practitioners and groups of two to nine EPs, while preserving the emphasis on provision of high quality efficient and effective care. We are finalizing revisions to §§414.1230, 414.1270, and 414.1265 to reflect these final policies.

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 proposed 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 proposed 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. We provided several examples to illustrate the proposal.

We believe our proposed approach is appropriate because it is straightforward for TINs participating in multiple Shared Savings Program ACOs to understand. The 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. It also allows us to determine peer group means for the purposes of determining statistical significance and determining whether a given quality composite score is at least one standard deviation from the peer group mean. We proposed to make corresponding changes to §414.1210(b)(2).

In developing this 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 solicited comments on our proposal as well as the alternatives we considered.

The following is a summary of the comments we received on the proposal and

alternatives considered:

Comment: We received a few comments in support of our proposal to assign practices the highest quality composite score of the multiple ACOs in which they participated. One commenter expressed the belief that in the instance where a group or individual EP participates in two or more ACOs, it is more appropriate and straightforward to compare the VM adjustments associated with each ACO and apply the highest VM adjustment to the group or individual EP. We received no comments on the alternatives we considered.

Response: We appreciate commenters' support of our proposal to assign TINs participating in multiple Shared Savings Program ACOs the quality composite score of the ACO with the highest numerical quality composite score. We acknowledge the comment that it would be more straightforward to apply the highest VM adjustment instead; however, it would not be possible to assign the highest VM adjustment to these TINs, because movement of a given TIN from one quality designation to another (from average to high quality, for example) would result in recalculation of the peer group mean against which all other TINs subject to the VM are compared, for the purpose of determining their quality designations. Such a recalculation would necessitate an additional analysis of which Shared Savings Program ACO had the highest numerical quality composite score. Likewise, movement of another TIN from one quality designation to another would necessitate the same recalculation. Thus, it would not be feasible for us to concurrently recalculate the VM for every TIN, with each iteration of moving a given TIN in and out of a peer group mean.

Final Policy: After consideration of the comments received, we are finalizing our proposal that, beginning with the CY 2017 payment adjustment period, TINs that participate in multiple Shared Savings Program ACOs in the applicable performance period will receive the quality composite score of the ACO that has the highest numerical quality composite score. We

believe that this is the most straightforward and advantageous methodology to acknowledge the highest quality performance among the Shared Savings Program ACOs in which these TINs participate.

(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)). As noted above, ACO participants who do not provide primary care services may participate in multiple Shared Savings Program ACOs, but under section 1899(b)(4) of the Act, providers and suppliers that participate in a Shared Savings Program ACO may not participate in an Innovation Center model that involves shared savings, or any other program or demonstration project that involving shared savings. 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 in section III.M.4.e. of this final rule with comment period. We proposed 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 proposed to make corresponding changes to §414.1210(b)(2)(i)(E). We solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: We received one comment in support of our proposal of applying the VM to groups and solo practitioners who participate in the Medicare Shared Savings Program, even if they also participate in an Innovation Center model. Two commenters were of the opinion that the proposed policy would be a barrier to fostering innovation and expressed the concern that a TIN's performance might be counted multiple times if it participates in the Shared Savings Program, an Innovation Center initiative, and the VM. Though we made no proposals to do so, the majority of comments on proposals surrounding application of the VM to Shared Savings Program ACO participant TINs expressed support for waiving the VM for these TINs entirely.

Response: We appreciate the commenter's support for our proposal to apply the VM to Shared Savings Program participants, even if they also participate in Innovation Center models, as it would incentivize the provision of high quality care to assigned beneficiaries. We also note that the quality measures used for calculating the VM quality composite score for Shared Savings Program ACO participants are the same measures under which their quality is measured within the Shared Savings Program, and they are assigned a cost composite score of "average" under the VM. Consequently, they do not face conflicting quality or cost performance incentives or increased reporting burden. With regard to the comment that application of the VM to Shared Savings Program ACO participants would create a barrier to innovation under Innovation Center models, we disagree. The quality performance of these TINs under the Shared Savings Program is used for purposes of calculating the VM quality composite score. No additional requirements related to cost or quality reporting are imposed on these TINs for purposes of the VM, above what they are already doing under the Shared Savings Program, so no additional barriers to

innovation would be created by applying the VM. A TIN's performance under an Innovation Center model is not considered under the VM and is therefore not counted multiple times.

Final Policy: After consideration of the public comments received, we are finalizing our proposal, beginning with the CY 2017 payment adjustment period, to 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 revised §414.1210(b)(2)(i)(E) to reflect this policy. This will avoid the need to create multiple policies for application of the VM to Shared Savings Program participant TINs and will continue to reinforce the importance of quality performance.

(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 proposed 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 proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: We received one comment questioning this proposal, in which the commenter expressed the belief that the proposal would discourage participation in Shared Savings Program ACOs due to the potential to earn a downward payment adjustment under the VM.

Response: We disagree that the proposed policy would discourage participation in Shared Savings Program ACOs. Shared Savings Program ACOs are required to report on quality on behalf of all participants and this provision reinforces that reporting requirement. If these TINs did not participate in a Shared Savings ACO, they would be required to meet quality reporting requirements for the VM through another mechanism. We believe that the proposed policy would emphasize the importance of quality performance while treating Shared Savings Program participant TINs the same as other TINs with regard to the consequence of failing to report quality data.

Final Policy: After consideration of the comments received, we are finalizing our proposal for the CY 2018 payment adjustment period, that if a Shared Savings Program ACO does not successfully report quality data as required by the Shared Savings Program during the performance period for the VM, all groups and solo practitioners participating in the ACO will

fall in Category 2 for the VM and will be subject to an automatic downward payment adjustment. We are finalizing the corresponding revisions to §414.1210(b)(2)(i)(D).

(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 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 proposed a similar policy for the CY 2018 payment adjustment period as discussed in section III.M.4.f. of this final rule with comment period.

Beginning in the CY 2017 payment adjustment period, we proposed 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 proposed 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 proposed corresponding revisions to §414.1210(b)(2). We solicited 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 noted 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.

The following is a summary of the comments we received on this proposal.

Comments: Commenters were very supportive of this proposal. One commenter encouraged CMS to include aspects of social risk or community risk in the calculations, stating that achieving good quality results for patients who are socially complex (for example, low income, homeless, living alone) or living in unsupportive community environments would justify the same kind of enhanced payment that achieving similar outcomes for clinically complex patients does, which supports the idea of adding an upward payment adjustment in 2017 and subsequent years of the VM program to those treating high-risk beneficiaries.

Response: We acknowledge that beneficiaries' social support systems could potentially

have an impact on quality performance. We did not make any proposals to change the definition of high-risk beneficiaries, however, and make no changes in this final rule with comment period.

Final Policy: After consideration of the comments received, we are finalizing our proposal beginning in the CY 2017 payment adjustment period 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 are finalizing corresponding revisions at §414.1210(b)(2). We note that Shared Savings Program ACO participant TINs are eligible for the +1.0x adjustment under §414.1210(b)(2) based on the average beneficiary risk score of the attributed patient population of their ACO; they are not eligible for the similar +1.0x adjustment under §414.1275(d).

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, and the timing and availability of that quality data may not be aligned with the availability of quality data under PQRS that is used in the VM calculations.

(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 the CY 2016 PFS proposed rule, and in consideration of comments previously received, we believed 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 proposed 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) of the Act for this purpose, will no longer apply in CY 2019 when the Value Modifier adjustment under section 1848(p) of the Act has ended. 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. We refer readers to the proposed rule (80 FR 41900) for an explanation of our rationale for proposing to waive the VM for the CPC Initiative and the Pioneer ACO 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 proposed the waiver would apply beginning with the CY 2017 payment adjustment period. We noted 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 noted 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 proposed to revise § 414.1210(b)(3) to reflect these proposals and sought comment on these

proposals.

(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 previously finalized 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 proposed 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 determined such a waiver would be 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 noted that this policy and use of the waiver authority under section 1115A(d)(1) of the Act 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 proposed to revise §414.1210(b)(4) to reflect this proposal. We solicited comment on this proposal.

(a) Application of the VM to Solo Practitioners and Groups with EPs Who Participate in the Comprehensive ESRD Care Initiative (CEC), Oncology Care Model (OCM), 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 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. We refer readers to the proposed rule (80 FR 41901) for an explanation of our determination that these models are similar to the Pioneer ACO Model and the CPC Initiative and our belief that a waiver is necessary to test these models.

We proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on the proposals to waive application of the VM for the Pioneer ACO Model; CPC Initiative; and other similar Innovation Center models, including the Next Generation ACO Model, Oncology Care Model, and Comprehensive ESRD Care Initiative.

Comment: We received many comments on this proposal, all of which were in support of waiving the VM if at least one EP participated in the Pioneer ACO Model, CPC Initiative, or other similar Innovation Center model, such as Next Generation ACO, Oncology Care Model, or the Comprehensive ESRD Care Initiative. Though we did not make any proposal to do so, several of the commenters also requested that CMS also waive the VM for EPs who participate in the Medicare Shared Savings Program. A few commenters suggested that the Value Modifier be waived for participants in any Alternative Payment Model (APM), even for private (non-CMS) demonstrations, and also suggested waiving the Value Modifier for the Bundled Payments for Care Improvement (BPCI) initiative.

Response: We appreciate commenters' support for our proposal to waive the VM for these models. With regard to the suggestion that we also waive the VM for Shared Savings Program ACO participants, we disagree that such a waiver would be appropriate or necessary to carry out the Shared Savings Program. As stated in the CY 2015 final rule with comment period

(79 FR 67941), we believe that alignment of the VM and the Shared Savings Program emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. The Shared Savings Program requires quality reporting through the PQRS GPRO Web Interface, so we have readily available quality data for use in calculating a quality composite score for the VM, whereas such data may not be available for TINs that participate in Innovation Center models. The VM does not impose any different quality performance requirements on Shared Savings Program ACO participants, and thus does not create conflicting quality performance incentives for them. We disagree with the commenters' suggestion that we waive the VM for participants in any APM, BPCI or private (non-CMS) demonstrations. If the commenters are referring to APMs as defined in section 101(e) of MACRA, we note the statutory amendments made by this section have payment implications for EPs beginning in 2019, after the VM has sunset. We established specific criteria for a model to be considered "similar," for the purpose of waiving the VM. The VM is an important initiative for incentivizing high quality efficient care for Medicare beneficiaries. We established specific criteria wherein it could be waived and we do not believe that it would be appropriate to waive this important adjustment in cases where the criteria do not apply. We do not believe BPCI is a "similar" model according to the criteria established in the CY 2015 PFS final rule with comment period (79 FR 67949 through 67950), because the model does not require reporting on quality measures outside of the PQRS, does not require reporting on cost measures, and its methodology is not in conflict with the cost and quality metrics used under the VM.

Final Policy: After considering the public comments received, we are finalizing our proposals to waive application of the VM for the Pioneer ACO Model; CPC Initiative; and other similar Innovation Center models, including the Next Generation ACO Model, the Oncology

Care Model, and the Comprehensive ESRD Care Initiative, all as proposed without modification. We are finalizing the corresponding revisions to the regulation text at §414.1210(E)(3)(i)(ii)

(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 finalizing in section III.M.4.e.1. of this final rule with comment period our proposal 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, we stated in the event that we finalize the waiver, we proposed to remove the references to “CMS initiatives” from §414.1210(b)(4). We solicited comment on this proposal, but did not receive comments specific to this proposal.

Final Policy: As a result, we are finalizing our proposal to remove the references to “CMS initiatives” from §414.1210(b)(4).

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 final rule with comment period, under section

1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the MIPS that shall apply to payments for items and services furnished on or after January 1, 2019. To maintain stability in the payment adjustment amounts applicable under the VM as we transition to the MIPS in 2019, we proposed 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 final rule with comment period that in CY 2018 we proposed 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 proposed 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 proposed 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 percent for groups classified as either low quality/average cost or average quality/high cost. We also proposed 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 (80 FR 41903) of the proposed rule shows the quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These 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 proposed to apply a negative “-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 negative “-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 negative “-1.0” percent for groups and physician solo practitioners classified as either low quality/average cost or average quality/high cost. We also proposed 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 of the proposed rule (80 FR 41903) shows the 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 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 proposed to apply a negative “-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 noted in section III.M.4.b. of this final rule with comment period, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We also proposed 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 of the proposed rule (80 FR 41903) shows the 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 have received 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 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 proposed 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 proposed to revise §414.1270 and §414.1275(c)(4) and (d)(3) to reflect the changes to the payment adjustments under the VM for the CY 2018 payment adjustment period. We solicited comments on all of these proposals.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), we noted 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 35 of the proposed rule) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

The following is a summary of the comments we received on these proposals.

Comment: Several commenters expressed appreciation for our efforts to maintain stability in the payment adjustment amounts applicable under the VM in CY 2018 as we transition to the MIPS in CY 2019 and supported our proposal to maintain the payment adjustment amounts in CY 2018 at the same levels as that for the CY 2017 VM. Some commenters suggested alternatives that included maintaining lower downside risk while establishing different upward adjustments based on group size; keeping adjustments constant, regardless of group size; and establishing a 2.0 percent maximum amount at risk for all groups, so that combined with the PQRS adjustment, the total would be consistent with the 4.0 percent at risk under the first year of the MIPS.

Response: We appreciate the commenters’ support of our proposals. We believe that any significant change in the payment adjustment amounts under the VM from CY 2017 to CY 2018, which is the final year in which the VM will apply to payments, would not be consistent with our intention to maintain stability as we transition to the MIPS in CY 2019.

Final Policy: As discussed in section III.M.4.c. of this final rule with comment period, for the CY 2018 VM, we are finalizing that we will continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We are also finalizing that groups and solo practitioners will 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 comment period (79 FR 67937), that groups consisting 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. We finalized modifications to ensure that the measures used to calculate the VM for solo practitioners and groups of all sizes are reliable, in sections III.M.4.c. and III.M.4.k. of this final rule with comment period.

For CY 2018, we are finalizing that we will apply a negative “-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 will set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to negative “-4.0” percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as low quality/high cost and set the adjustment to negative “-2.0” percent for groups classified as either low quality/average cost or average quality/high cost. We will also 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 set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. Table 47 shows the final quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These payment amounts will 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 are finalizing that we will apply a negative “-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 will set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to negative “-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 set the adjustment to negative “-1.0” percent for groups

and physician solo practitioners classified as either low quality/average cost or average quality/high cost. We will also 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 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 48 shows the final 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 payment adjustment amounts will 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 are finalizing that we will apply a negative “-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 finalized in section III.M.4.b. of this final rule with comment period, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We are also finalizing 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 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. 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 49 shows the final 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. 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 will be available to all groups and solo practitioners eligible for upward adjustments under the VM. Consequently, the upward payment adjustment factor (“x” in Tables 47, 48, and 49) will be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

TABLE 47: Final CY 2018 VM Amounts for the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs in Groups of Physicians with Ten or More EPS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	+2.0x*	+4.0x*
Average cost	-2.0%	+0.0%	+2.0x*
High cost	-4.0%	-2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting 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 48: Final CY 2018 VM Amounts for the Quality-Tiering Approach for Physicians, PAs, NPs, CNSs, and CRNAs in Groups of Physicians 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 49: Final 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.

Comment: Commenters supported our proposal 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 treated the most complex beneficiaries. One commenter urged CMS to apply the additional upward payment adjustment to all providers that serve high-risk patients, and another stated that CMS should include aspects of social risk or community risk in the determination of whether beneficiaries fall into the highest risk category.

Response: The additional upward payment adjustment is intended to be an incentive for groups and solo practitioners that treat high-risk beneficiaries to provide them with higher quality of care at lower costs. Therefore, we do not believe it would be appropriate to provide the additional upward payment adjustment to all groups and solo practitioners that treat high-risk beneficiaries. As discussed in section III.M.4.d. of this final rule with comment period, we did not make proposals to include aspects of social or community risk in the determination of whether a beneficiary would be classified as falling in the top 25 percent of risk scores, such that a TIN treating the beneficiary would be eligible for the additional +1.0X adjustment, and thus make no such adjustments in this final rule with comment period.

Final Policy: We are finalizing our proposal 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.

Comment: One commenter noted the following clarification provided for the PQRS program in section III.I.1. of the proposed rule: “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.” The commenter requested that we also clarify that EPs who practice in RHCs and/or FQHCs would not be subject to the VM.

Response: As discussed in the CY 2013 PFS final rule with comment period (77 FR 69309), the VM provides for differential payment to a physician or a group of physicians under the Medicare PFS for items and services furnished. Groups and solo practitioners who furnish items and services paid under the Medicare PFS are subject to the VM for these items and services, regardless of whether they practice in RHCs and/or FQHCs. However, as explained in section III.I.1. of the proposed rule (80 FR 41816), we are currently unable to assess PQRS participation for EPs billing under the PFS who practice in RHCs and/or FQHCs and do not also practice in other settings, such as in physician offices. Under the PQRS, these EPs will be treated as having avoided the PQRS payment adjustment if the EP billing under the PFS reports only place of service codes 50 (FQHC) and/or 72 (RHC) during the applicable reporting period. As discussed in section III.M.4.c. of this final rule with comment period, a TIN will be included in Category 1 if the TIN meets the criteria to avoid the PQRS payment adjustment as a group or at least 50% of the EPs in the TIN meet the criteria to avoid the PQRS payment adjustment as individuals. Further, consistent with the policy we are finalizing in section III.M.4.m. of this final rule with comment period, a group or solo practitioner will 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.

Comment: One commenter was concerned that there is no process that would permit nonparticipating physicians to receive an upward adjustment under the VM.

Response: We refer the commenter to the CY 2015 PFS final rule with comment period (79 FR 67950-67951), in which we explained that the VM will apply to all assigned claims, including those submitted by both participating and non-participating physicians, and nonphysician EPs to the extent the VM is applied to them. Therefore, the VM will affect nonparticipating physicians to the extent that they submit assigned claims, and they may qualify for an upward adjustment under the quality-tiering methodology the same as a participating physician. We will monitor these issues, but we continue to believe that these policies are reasonable. As explained in previous rulemaking (79 FR 67950-67951), if the VM were to be applied to non-assigned services, then the VM would directly affect beneficiary cost sharing and not Medicare payments to physicians, contrary to our intent. We further note that over 99 percent of Medicare physician services are billed on an assignment related basis by both participating and non-participating physicians and other suppliers, with the remainder billed as non-assigned services by non-participating physicians and other suppliers (79 FR 40505).

Final Policy: After considering the comments received, we are finalizing all of the policies discussed in section III.M.4.f. of the proposed rule. We are also finalizing the revisions at §414.1270 and §414.1275(c)(4) and (d)(3) to reflect these policies without modification.

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 also proposed a

similar policy for the CY 2018 VM as discussed in section III.M.4.f. of the proposed rule (80 FR 41903). 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 proposed 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 solicited public comment on this proposal.

Final Policy: We did not receive any comments on this proposal. Therefore, we are finalizing our proposal and will 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.

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 proposed to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. Accordingly, we proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported our proposal to use CY 2016 as the performance period for the 2018 VM, while another commenter objected stating that it is difficult for groups to translate how performance affects payments two years later and urged CMS to eliminate the gap between performance and payment years. One commenter asked that we clarify whether CY

2016 will be the last performance period for the VM program.

Response: In the CY 2012 PFS final rule with comment period (76 FR 73435), CY 2013 PFS final rule with comment period (77 FR 69313-69314), and CY 2014 PFS final rule with comment period (78 FR 74771-74772), we addressed how we considered shortening the gap between the performance period and the payment adjustment period. As we explained in the CY 2012 PFS final rule with comment period (76 FR 73435), we explored different options to close the gap between the performance period and the payment adjustment period, but found that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate a VM and notify physicians and groups of physicians of their quality and cost performance and VM prior to the payment adjustment period.

As discussed in section III.M.5.a. of this final rule with comment period, in April 2015, we made available 2014 Mid-Year QRURs to groups of physicians and physician solo practitioners nationwide based on performance from July 1, 2013, through June 30, 2014. We plan to make available the 2015 and 2016 Mid-Year QRURs during the spring of 2016 and 2017, respectively. The Mid-Year QRURs are intended to provide groups and solo practitioners with interim information about their performance on the claims-based quality outcome measures and cost measures that are a subset of the measures that were used to calculate the VM. Therefore, we are finalizing our proposal to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018.

As discussed in section III.M.4.b. of this final rule with comment period, 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. Therefore, CY 2018 will be the final payment adjustment period and CY 2016 will be the final performance

period under the VM.

Final Policy: After considering public comments received, we are finalizing our proposal to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018 and finalizing the addition of §414.1215(d) without modification.

i. Quality Measures

(1) PQRS Reporting Mechanisms

In the CY 2016 PFS proposed rule (80 FR 41904), we stated our belief that 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 sought to avoid placing an undue burden on EPs to report such data. Accordingly, for purposes of the VM for CY 2018, we proposed 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 the proposed rule (80 FR, 41825).

(2) PQRS Quality Measures

We proposed 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 the proposed rule (80 FR 41830).

The following is the summary of comments we received on these proposals.

Comment: Commenters supported the continued alignment of the VM with PQRS requirements. However, some commenters raised concerns about the lack of applicable measures for multiple specialties.

Response: We thank the commenters for their support of our continued alignment with PQRS. In previous rulemakings we have committed to expanding the specialty measures available in PQRS to more accurately measure the performance on quality of care furnished by specialists; PQRS now has specialty measure sets (for example; Pathology preferred measure set, radiology preferred measure set, and ophthalmology preferred measure set) that can be utilized as a guide to assist eligible professionals in choosing measures applicable to their specialty. We reaffirm our commitment to using measures of performance across specialties that are valid and reliable for the VM. As discussed in section III.M.4.m. of this final rule with comment period, we are finalizing that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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.

Final Policy: After consideration of the comments received, we are finalizing our proposal for the CY 2018 VM to include 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 27 and 28 of this final rule with comment period. Additionally, we are finalizing our proposal 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 quality measures are described in Table 29 through 42 of this final rule with comment period.

(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 made a proposal to address this issue. We referred to quality measures collected through EHRs as “eCQMs.” We noted 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 proposed 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 proposed 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 solicited comment on this proposal. The following is a summary of the comments we received on this proposal:

Comment: Commenters were unanimous in their support of this proposal. However, while not directly related to this proposal several commenters asked for clarification on how benchmarks for quality of care measures reported via PQRS QCDRs will be calculated. Specifically, they asked whether QCDR measures would only be benchmarked against identical measures that are reported via a different QCDR or other reporting mechanism. Commenters also requested clarification on whether QCDRs will be allowed to develop their own benchmarking methodology or if CMS plans to calculate the benchmarks using its current methodology.

Response: PQRS measures reported via QCDRs will be benchmarked according to our current VM benchmarking methodology which is defined as follows. The benchmark for quality of care measures reported through the PQRS using the claims, registries, QCDR, 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. Benchmarks for non-PQRS quality of care measures reported via QCDRs would also be calculated as the national mean of the measure's performance rate across all EPs reporting the measure via different QCDRs during the year prior to the performance period. It is important to note that measures reported through a QCDR that are new to PQRS would not be included in the quality composite for the VM because we would not be able to calculate benchmarks for them.

Final Policy: After consideration of the comments received, we are finalizing our proposal to exclude eCQM measures from the overall benchmark for a given measure and create separate eCQM benchmarks, based on the CMS eMeasure ID beginning with the CY 2016 performance period for which the eCQM benchmarks would be calculated based on CY 2015 performance data. We will finalize corresponding changes to §414.1250(a).

(4) CAHPS Reporting

In our efforts to maintain alignment with the PQRS quality reporting requirements, we noted in the proposed rule that the criteria for administration of the CAHPS for PQRS survey for the CY 2016 performance period will contain 6 months of data (80 FR 41904). 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 VM, should they elect to have CAHPS for PQRS included in their VM calculation. 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 VM (77 FR 69322-69323). We noted that we took a similar approach in the CY 2014 PFS final rule with comment period (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 with comment period (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 proposed to continue this policy for the CY 2016 performance period for the CY 2018 VM. We did not receive comments on this proposal, and therefore, are finalizing our policy that groups with 2 or more EPs could elect to include the patient experience of care measures collected through the PQRS CAHPS survey for the CY 2016 performance period for the CY 2018 VM. We note that this policy for the VM is separate from the CAHPS reporting requirements under the PQRS.

(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 proposed 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 proposed 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 proposed 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 proposed to make corresponding changes to §414.1210(b)(2)(i)(B). We solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported this proposal, and we did not receive any opposing comments.

Response: We thank the commenter for their support.

Final Policy: After consideration of the comments received, we are finalizing our proposal 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 are also finalizing 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 finalized corresponding changes to §414.1210(b)(2)(i)(B).

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 intended to disseminate reports containing CY 2013 data in fall 2014 to groups of physicians subject to the VM in 2015 and that we would 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) 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 physicians to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). Our intent was to design this process as a means to recompute a TIN’s quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We noted that if the operational infrastructure was not available to allow this recomputation, we would continue the approach for the CY 2015 payment adjustment period to classify a TIN as “average quality” in the event we determine that we have made an error in the calculation of the quality composite. We finalized that we would recalculate the cost composite in the event that an error was made in the cost composite calculation. We noted that we would provide additional operational details as necessary in subregulatory guidance.

Moreover, for both the CY 2015 payment adjustment period and future adjustment periods, we finalized a policy to adjust a TIN’s quality-tier if we make a correction to a TIN’s quality and/or cost composites because of this correction process.

We further noted that there is no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act. In the CY 2015 final rule for the CY 2016 payment adjustment period, we noted that if the

operational infrastructure is not available to allow the recomputation of quality measure data we would continue the approach of the initial corrections process to classify a TIN as “average quality” in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite. We proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: Many commenters supported this proposal; however, several commenters cautioned about the over-reliance on the automatic “average quality” designation as it may not accurately reflect the quality of truly high performers and may penalize physicians for errors that are outside of their control. One commenter also suggested extending the review period to ninety days to give practitioners enough time to thoroughly review the QRURs.

Response: We acknowledge commenters’ concerns about the “average quality” designation; however we continue to believe the proposal to assign “average quality” if it is not possible for us to recompute the quality composite is the best alternative in light of the quality data that will be available during the informal inquiry process and prior to application of the VM adjustments. We believe that a 60-day review period allows ample time for practitioners to access and review their QRURs. The 60-day timeframe also enables us to make corrections prior to the start of the payment adjustment period, reducing administrative burden and costs of reprocessing claims for both physicians and CMS.

Final Policy: After consideration of the comments received, for the CY 2017 and CY 2018 payment adjustment periods, we are finalizing a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner

to request a correction of a perceived error related to the VM calculation. We are finalizing the continuation of the process for accepting requests from groups and solo practitioners to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). We would continue the approach of the initial corrections process to classify a TIN as “average quality” in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite and the infrastructure was not available to allow for recomputation of the quality measure data.

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 PQRS 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 PQRS and VM informal review submission periods 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 proposed 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

noted 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 would be classified as “average quality”; however, if the data is available in a timely manner, then we would recalculate the quality composite.

We solicited comments on this proposal. The following is a summary of the comments we received on this proposal:

Comment: Commenters were unanimous in their support for this proposal.

Response: We thank the commenters for their support.

Final Policy: After consideration of the comments received, we are finalizing our proposal 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 to avoid the PQRS downward payment adjustment for the relevant payment adjustment year. If the group was initially classified as Category 2, then we would not expect to have data for calculating their quality composite, in which case they would be classified as “average quality”; however, if the data is available in a timely manner, then we would recalculate the quality composite.

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 non-specialty-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 found that the specialty-adjusted measure did not have moderate or high reliability with a 20 episode minimum for many groups (80 FR 41906).

Given that our analysis demonstrated the measure had 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 proposed to increase the episode minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. We also noted that we had 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 noted that, using an episode minimum of 20 for the 2016 VM, the MSPB measure has moderate reliability for the 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).

We believe that it is important to ensure that only reliable measures are included in the VM. We also noted that we had considered increasing the episode minimum to 75 instead of 100. This would have allowed us to include the MSPB measure in the cost composite for a larger number of groups but we stated that we believed that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum.

Therefore, we proposed to add §414.1265(a)(2) to reflect a case minimum of 100 episodes for the MSPB measure beginning with the CY 2017 payment adjustment period and CY

2015 performance period. We solicited comment on this proposal, as well as on a 75-episode minimum or other potential minimum case thresholds for this measure.

The following is a summary of the comments we received on this proposal to establish a case minimum of 100 episodes for the MSPB measure.

Comment: Most commenters that responded to the proposal generally supported the proposal to increase the episode minimum to 100 episodes, given that the results for the specialty-adjusted measure were more reliable at higher episode minimums and that this would result in increased accuracy of the MSPB measure. Many commenters that supported the proposal also suggested that CMS consider an even higher minimum number of episodes (for example, 200 episodes). A few commenters opposed the proposal and/or suggested a lower minimum number of episodes such as 50. These commenters indicated their concern with a scenario we had discussed in the proposed rule in which a group that would have performed well on this measure would no longer have this measure included in its cost composite as a result of the proposal, which could negatively impact their TIN's cost composite score, and ultimately their VM adjustment. Some commenters suggested that any measures that cannot meet a reliability standard of at least 0.7 should be rejected.

Response: We appreciate the commenters' support for our proposal to raise the episode minimum for this measure. As discussed in section III.M.4.c. of this final rule with comment period, commenters expressed concerns over small sample sizes, as they related to application of downward adjustments under quality-tiering for solo practitioners and groups of two to nine EPs. In response to those comments, we conducted a more granular reliability analysis, based on which we determined a minimum of 125 episodes was required in order for this measure to meet our average reliability threshold of 0.4 for solo practitioners and groups of two to nine EPs (see Table 46 in section III.M.4.c. of this final rule with comment period). Based on this new

analysis, we believe that a minimum of 125 episodes is preferable to the reliability associated with the other minimum numbers of episodes suggested by some commenters. For example, a 50 or 75 episode minimum 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 and groups of two to five EPs with a minimum of 125 episodes is preferable to the reliability when using a 50 or 75 episode minimum. As discussed in the proposed rule, establishing a higher case minimum reduces the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite. Our latest analysis supports this finding, with 6,401 TINs having 125 or more cases for MSPB, as compared to the 7,904 TINs had 100 or more cases, based on 2014 data. However, we do not believe we should use the measure in calculating the cost composite if it is not reliable. Further, we believe that a minimum of 125 episodes is preferable to a higher minimum such as 200 episodes suggested by some other commenters. A higher minimum might slightly increase the reliability of the measure but would further reduce the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite.

We acknowledged in the proposed rule (80 FR 41906) 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 continue to believe that it would not be appropriate to include this measure in the cost composite with a 20-episode minimum at a sample size that does not produce reliable results 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.

Final Policy: After consideration of the comments received, we are finalizing an episode minimum of 125 episodes for the MSPB measure beginning with the CY 2017 payment adjustment period and CY 2015 performance period. We are finalizing an addition at §414.1265(a)(2) to reflect this final policy.

1. 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 proposed that, beginning with the 2018 VM, we change the definition of index admission used for the MSPB measure 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 in other states. Under this proposal, we would continue to standardize 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 for payment policy changes and updates; any methodological changes made across years are documented in the Appendix of the “CMS Price Standardization” document. We solicited 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.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported the proposal and we did not receive any opposing comments.

Response: We appreciate the commenter’s support for the proposal. This change will allow us to include this measure in the calculation of the cost composite for groups and solo practitioners in Maryland, consistent with what is done in other states.

Final Policy: After consideration of the comments received, we are finalizing the proposal to, beginning with the CY 2018 payment adjustment period, include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM.

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 final rule with comment period, beginning with the CY 2017 payment adjustment period, we proposed to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes. Therefore, we proposed 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 proposed 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 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 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 proposed 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 proposed 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 final rule with comment period, 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 proposed 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 proposed to specify in §414.1265(b)(1) that this policy was applicable only for the CY 2015 payment adjustment period.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported our proposal to classify a quality or cost composite as “average” if there is not at least one quality or cost measure that can be calculated reliably. Some commenters were concerned that some practices would be subject to a downward adjustment under the quality-tiering methodology if classified as “average cost and low quality” or “average quality and high cost” under the proposed policies and recommended that any group

or solo practitioner that receive an automatic average designation due to a lack of either quality or cost measure data should be held harmless from any downward payment adjustment under the VM.

Response: After considering comments we received, we are finalizing all of the policies as proposed. We believe that for TINs for which we are not able to calculate a reliable quality (or cost) composite score, it is appropriate to classify the quality (or cost) composite as average under the quality-tiering methodology and determine the VM adjustment based on the TIN's available cost (or quality) data.

In our analysis of the groups that are subject to the 2016 VM (without accounting for the informal inquiry process), we found that no TIN received a downward adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost under this policy. We also found that 2 TINs received an upward adjustment under the quality-tiering methodology as a result of being classified as average quality and low cost under this policy. Therefore, we expect these policies to have minimal negative impact on groups and solo practitioners.

Final Policy: As discussed in section III.M.4.k. of this final rule with comment period, beginning with the CY 2017 payment adjustment period, we are finalizing our proposal to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 125 episodes. Therefore, we are finalizing our proposed revisions to §414.1265(b) to indicate that a group or solo practitioner subject to the VM will 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. Consequently, to the extent a group or solo practitioner's quality composite is

classified as high, average, or low, the group or solo practitioner's VM will reflect that classification. To improve the organization of the regulation text, we are also finalizing our proposal to move the provisions at §414.1270(b)(5) and (c)(5) to §414.1265(b)(3).

We are finalizing that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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 will reflect that classification. We are finalizing the incorporation of this policy at §414.1265(b)(2). This policy is consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67934), that beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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 and thus a reliable cost composite cannot be calculated for the group or solo practitioner.

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 final policies that 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 and 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, we are also finalizing our proposal 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 proposed 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 physicians 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 noted 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 proposed 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 noted that we were 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).

We did not receive any comments on these proposals, and therefore, we are finalizing these technical changes to the regulation text without modification.

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 physician or other eligible professional. 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. As discussed in section III.M.4.c. of this final rule with comment period, we also note that the VM methodology includes additional safeguards to guard against misclassification—we finalized in the CY 2013 PFS final rule with comment period (77 FR 69325) the adoption of the quality-tiering model where we classify quality composite scores and cost composite scores each into high, average, and low categories based on whether these scores are at least one standard deviation from the mean and statistically significantly different from the mean at the 5.0 percent level of significance, in order to apply the VM bonus or penalty only when a group's performance is significantly different from the national mean.

We noted that high costs within the post-acute and long-term care settings present a unique opportunity for these professionals to improve performance on cost and quality measures. Although we continue to encourage professionals 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 did not make any proposals on this matter at this time. We solicited feedback on this potential approach, as well as other

approaches. The following is a summary of the comments we received on this potential approach.

Comment: Nearly all that provided feedback were supportive of approaches 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. Many of these commenters provided additional suggestions and/or reserve final judgment until an evaluation of the impact of this approach is made public. Some believe that we should address other methodology concerns such as to distinguish between specialists and sub-specialists in the same field or between physicians with similar training but very different practice profiles such as primary care physicians who are office-based versus those who are largely providing care in a hospital, skilled nursing facility or patient's home.

Response: We appreciate the thoughtful suggestions regarding the development of ways 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.

After consideration of the comments received, we will continue to work with stakeholders to further explore options for risk stratified comparisons. If we determine that further changes may be appropriate, we will make a proposal through future rulemaking. We will continue to learn from and incorporate more information about this issue and impacted groups in the annual experience report.

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 expanded 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 made 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 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 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 provides 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 accommodates new PQRS reporting options, including QCDRs and CAHPS for PQRS. In addition, the reports 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 provided more detailed per capita cost of service breakdowns for all six cost measures. The reports also 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 will disseminate 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 invited comment on which aspects of the QRUR reports have been most useful and how we can improve access to and usability of performance reports.

The following is a summary of the comments we received.

Comment: Commenters were supportive of CMS's intention to make QRURs 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 and Shared Savings Program ACO participant TINs and groups that include one or more EPs who participated in a Pioneer ACO or the CPC Initiative. However, commenters expressed concerns about timeliness of reports; the accessibility of the reports; the complexity of the reports, and the outreach regarding the VM program.

Response: In response to previous comments about the timeliness of reports, this year we disseminated the Mid-Year QRURs, the Annual QRURs and the Supplemental QRURs. We believe that these reports provide groups and solo practitioners with more timely and actionable information on the quality and cost of the care they furnish. We acknowledge that there is a process that must be followed to access the reports and would note that it is important to protect the information contained in the reports. These security measures are necessary to protect the

data contained in the reports and ensure that only authorized users are able to access them. We have made strides to simplify the outreach around how to access the reports and would direct readers to the step-by-step instructions at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html>. We also acknowledge that the QRUR reports could be perceived as complex. They contain a significant amount of valuable data to help physicians and other eligible professionals understand and improve the quality and efficiency of care they provide. We have added a performance dashboard to provide a visual snapshot and summary of performance to the beginning of the reports. We encourage all physician groups and solo practitioners to access their report and also encourage QRUR users to submit feedback to the PV helpdesk at 1-888-734-6433 (select option 3) or at pvhelpdesk@cms.hhs.gov. We have continued to engage our stakeholders and seek input on how best to refine the reports. We disagree that CMS does not provide adequate outreach about the VM. We conduct National Provider Calls in conjunction with each QRUR release, and we provide education and outreach documents that are accessible on our website related the VM, how to access the QRURs, and how to interpret the QRURs. We will continue to engage the stakeholder community to determine how best to educate about value-based payment programs.

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 provided 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 were 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, 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 included 26 major episode measures and 38 sub types of episodes and were made available to over 300,000 groups and solo practitioners. We will continue to seek stakeholder input as we develop the episode framework.

Lastly, we direct readers to the Physician Compare policies in this rule (section III.H. of this final rule with comment period), which did not finalize the proposal to add a green check mark to the profile page of the Physician Compare website for physicians and other eligible professionals receiving an upward adjustment under the VM starting in CY 2018. More information is available about Physician Compare on the CMS website 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; (3) prohibitions on per-unit of service (“per-click”) and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of “entity.” We are aware of the recent D.C. Circuit decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015), which addressed the

prohibition on per-click equipment lease payments found in §411.357(b)(4)(ii)(B). In accordance with that decision, the regulation has been remanded to the Secretary for further consideration. Accordingly, we are considering our options as to how to comply with the court's decision.

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 to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

b. Purpose of this Final Rule with Comment Period

This rule updates 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 those goals, the final rule with comment period 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 the proposed rule, we proposed to establish new policies and revise certain existing policies regarding recruitment assistance and retention payments. Specifically, we proposed a new exception for assistance to physicians to employ nonphysician practitioners (NPPs). In addition, we proposed to clarify for federally qualified health centers (FQHCs) and rural health clinics (RHCs) how to determine the geographic areas that they serve for the 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 also proposed 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 proposed to clarify how parties should calculate the maximum amount for permissible retention payments. Those proposals are described in detail below.

a. Assistance to Compensate 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 to be a member of the hospital’s medical staff, subject to certain requirements. This exception is codified at §411.357(e). In Phase III, we declined to expand §411.357(e) to cover the recruitment of NPPs into a hospital’s service area, including into an existing group practice (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. The demand for primary care is increasing, especially in rural and underserved areas,

because the Affordable Care Act expanded health care coverage to the previously uninsured, and because the population is growing and aging. The supply of physicians is projected to not keep pace with the increasing demand for primary care (see 80 FR 41910). We have identified similar trends with respect to mental health care services. NPPs, the fastest growing segment of the primary care workforce, may help to mitigate these shortages. In addition, new and evolving care delivery models, which feature an increased role for NPPs (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 NPP recruitment assistance to physicians, using the authority granted to the Secretary in section 1877(b)(4) of the Act, we proposed a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of an NPP.

The proposed exception at §411.357(x) would permit remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing an NPP in the geographic area served by the hospital, FQHC, or RHC providing the remuneration. (See 80 FR 41910 through 41911 for an explanation of how the proposed exception would 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.) The exception as proposed would have applied only where the NPP 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. However, we solicited comments regarding whether we should also permit remuneration to physicians to assist in attracting NPPs 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 NPP have a minimum term, such as 1 year).

Because our goal in proposing the exception at §411.357(x) was 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 proposed to define “nonphysician practitioner,” for the purposes of this exception, to include only physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse midwives (CNMs). We solicited comments regarding whether there is a compelling need to expand the scope of the proposed exception to additional types of NPPs who furnish primary care services.

We also proposed at §411.357(x)(1)(vi) a requirement that the NPP provide only primary care services to patients of the physician’s practice. We solicited comments regarding whether we should consider other, more, or fewer types of services to be “primary care services” for the purposes of proposed §411.357(x), whether there is a compelling need to expand the scope of the proposed exception to NPPs 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 proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician’s practice by the NPP: (1) at least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services. We proposed to define “substantially all” patient care services consistent with our regulations.

(See §411.352(d) and §411.356(c)(1).) We solicited comments regarding which of these alternatives is most appropriate and the nature of the documentation necessary to measure the NPP's services.

Because we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP's compensation and other practice costs, we proposed 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 NPP's employment by the physician. Under §411.357(x)(1)(iii) as proposed, the amount of remuneration from the hospital, FQHC, or RHC would have been capped at the lower of: (1) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the NPP; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the NPP from the actual salary, signing bonus, and benefits paid to the NPP by the physician. We proposed 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. Because the proposed exception would protect only remuneration to reimburse a physician for amounts actually paid to the NPP, the hospital, FQHC, or RHC providing the remuneration could not increase it to account for any tax implications to the physician. We solicited 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 NPP should include all receipts for all services furnished by the NPP, regardless of payor and regardless of whether the services were primary care services. We also solicited 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 NPP 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 an NPP. We also solicited comments specifically addressing the time limitations set forth in our proposal.

The proposed exception at §411.357(x) closely tracked 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 NPPs 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 NPPs.

We proposed requirements to safeguard against program or patient abuse similar to the requirements found in most of our exceptions in §411.357. Specifically, we proposed 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 NPP. In addition, the arrangement may not be conditioned on the physician's or the NPP'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 NPP (or any other physician or NPP in the physician's practice) or other business generated between the parties. Because 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 the purposes of the requirements of the new exception, we proposed at §411.357(x)(3) a definition of the term "referral" as it relates to NPPs that is modeled closely on the definition of a physician's "referral" at §411.351. We also proposed 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 proposed that records of the actual amount of remuneration provided to the physician (and to the NPP) be maintained for a period of at least 6 years and be made

available to the Secretary upon request. We solicited comment regarding whether these “general” safeguards are sufficient to protect against program or patient abuse resulting from arrangements to assist with NPP employment, or if additional safeguards are necessary.

We also proposed requirements for the compensation arrangement between the physician receiving remuneration and the NPP that the remuneration assists the physician to recruit. Specifically, we proposed that the aggregate salary, signing bonus, and benefits paid by the physician to the NPP must be consistent with fair market value. In addition, we proposed a requirement that the physician may not impose practice restrictions on the NPP that unreasonably restrict the NPP’s ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC, and stated that we would interpret this provision in the same way that we interpret the requirement at §411.357(e)(4)(vi) for physician recruitment arrangements.

We proposed to include requirements to prevent gaming by “rotating” or “cycling” NPPs 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 NPPs to the hospital, FQHC, or RHC. We noted our concern that parties may misuse the exception to shift to a hospital, FQHC, or RHC the costs of an NPP 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 proposed that the hospital, FQHC, or RHC may not provide assistance to a physician to employ an NPP if: (1) the NPP 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 the physician organization in whose shoes the physician stands); or (2) the NPP was employed or otherwise engaged by a physician (or a physician organization in whose shoes the physician stands) 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 (or the physician organization in whose shoes the physician stands), even if the NPP did not provide patient care services in that office. For consistency and to ease administrative burden, we proposed 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 an FQHC or RHC to have the same meaning assigned to this term in proposed §411.357(e)(6)(ii).

Finally, we solicited 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), including comments addressing whether we should limit the number of times a hospital, FQHC, or RHC may assist the same physician with the employment of NPPs and, if so, during what time period that limitation should apply. We sought comments on whether we should limit the use of the exception to no more than once every 3 years for a particular physician or no more than three times in the aggregate (regardless of time period) for a particular physician. We sought comments as to whether this type of limitation potentially undermines the goal of increased access to primary care in the event the NPP(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 were 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 solicited 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.

With several modifications, described below in response to the comments we received, we are finalizing an exception at §411.357(x) for remuneration provided by a hospital, FQHC, or RHC to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practice. The following is a summary of the comments we received.

Comment: Most commenters supported our proposal to permit remuneration from hospitals, FQHCs, and RHCs to assist physicians in employing NPPs, variously noting that this will increase access to quality healthcare nationwide at a time when healthcare workforce shortages are projected to increase, particularly in underserved and rural areas, and in light of a steadily rising tide of insured patients; be of great benefit to institutional providers of services, physicians, and NPPs; and benefit patients who would otherwise need to travel distances to obtain needed health care services.

Response: We agree with the commenters that the new exception codified at §411.357(x) will both promote beneficiary access to care and remove barriers that could frustrate health care delivery and payment system reform efforts. We believe that the exception, as finalized, includes appropriate safeguards to insure against program or patient abuse, yet is sufficiently flexible to achieve the outcomes described by the commenters. As described elsewhere in this section, we are expanding the scope of the exception to include remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing or contracting with an NPP. Therefore, we refer to new §411.357(x) as an exception for assistance to compensate an NPP. However, because the public comments addressed the proposal to establish an exception for assistance to "employ" an NPP, the comment summaries below reflect the use of that terminology. This does not affect final §411.357(x), which is an exception for assistance to compensate an NPP.

Comment: One commenter stated that we could achieve our policy of permitting a hospital to provide assistance to a physician to employ an NPP simply by permitting NPPs to be included in the existing exception for physician recruitment at §411.357(e).

Response: We disagree with the commenter. The exception for physician recruitment is statutory and covers only remuneration from a hospital to a physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. The Secretary's authority in section 1877(e)(5)(C) of the Act permits her to impose on the arrangement between the hospital and the recruited physician other requirements that she determines necessary to protect against program or patient abuse. This authority does not extend to an expansion of the exception to include remuneration to a physician to employ, contract with, or otherwise recruit an NPP.

We are utilizing the authority in section 1877(b)(4) of the Act to establish the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP. Because the exception for physician recruitment in section 1877(e)(5) of the Act and §411.357(e) of our regulations only permits remuneration to a physician to induce the physician to relocate his or her medical practice and join the medical staff of the recruiting hospital, we believe that a standalone exception addressing recruitment of an NPP is more appropriate.

Comment: Several commenters, although supportive of CMS' "efforts to think about creative solutions to the severe primary care shortage," opposed the proposed exception for NPPs. The commenters voiced concerns that the proposed exception will be used by hospitals to recruit nonphysician providers away from FQHCs, thereby exacerbating the primary care workforce shortage and worsening access issues for vulnerable safety-net populations.

Response: After carefully considering all of the comments, we are persuaded that the availability of the exception for assistance to compensate NPPs will improve access to care by

bringing more qualified healthcare providers to areas where they are needed. Although we understand the commenters' concerns, we are finalizing the exception at §411.357(x) with the modifications described elsewhere in this section.

Comment: Several commenters, using nearly identical language, described our proposed exception for payments to assist a physician in employing an NPP as protecting “both direct compensation arrangements between the hospital and an individual physician and ‘indirect’ compensation arrangements between the hospital and a physician ‘standing in the shoes’ of a physician organization to which the hospital provided remuneration.”

Response: As we explained in the proposed rule (80 FR 41910-11), the exception at §411.357(x) is available to protect a direct compensation arrangement between a hospital, FQHC, or RHC and a physician, including a compensation arrangement deemed to be a direct compensation arrangement because the physician stands in the shoes of his or her physician organization under §411.354(c)(1). We do not repeat this analysis here. The exception at §411.357(x) is not available for a compensation arrangement that qualifies as an “indirect compensation arrangement” under §411.354(c)(2). Parties wishing to except an indirect compensation arrangement from the law’s referral and billing prohibitions must utilize the exception at §411.357(p).

Comment: One commenter urged CMS to expand the scope of the exception to permit remuneration to advanced practice registered nurses and PAs to employ other advanced practice registered nurses and PAs. Another commenter requested that we expand the exception to permit “the same incentives” to a NP practice so that all eligible providers have equal opportunity to provide access to high quality, cost-effective Medicare services. A third commenter suggested that we permit the remuneration to flow “directly to” the NPP who is

joining a physician practice or “through” the physician practice that he or she joins, similar to the exception for physician recruitment at §411.357(e).

Response: In Phase III, we explained that recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician (72 FR 51049). This is because section 1877 of the Act is implicated only by the existence a financial relationship between a physician (or his or her immediate family member) and an entity to which the physician makes a referral for DHS payable by Medicare. Provided that the NPP is neither a conduit for physician referrals nor an immediate family member of a referring physician, the compensation arrangements described by the first two commenters would not implicate section 1877 of the Act and no exception to the law’s referral and billing prohibitions would be necessary. As to the third comment, provided that all of the remuneration from the hospital, FQHC, or RHC remained with the NPP (that is, the physician practice retained none of the remuneration as overhead or other expenses), the arrangement described by the commenter should not implicate the physician self-referral law. We caution, however, that an arrangement involving remuneration to a potential referral source may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Three commenters urged CMS to expand the scope of the exception to cover the employment of mental health care providers to address the acute need for mental health care services. Another commenter similarly suggested that we include clinical social workers and clinical psychologists within the scope of the exception.

Response: As described elsewhere in this section, we are finalizing the exception at §411.357(x) to permit remuneration to a physician who compensates an NPP to provide either primary care services or mental health care services to patients of the physician’s practice.

Accordingly, we are expanding the definition of “nonphysician practitioner” for the purposes of §411.357(x) to include clinical social workers and clinical psychologists, as well as PAs, NPs, CNSs, and CNMs.

Comment: We received numerous comments regarding the definition of “nonphysician practitioner” for the purposes of the new exception at §411.357(x), which was proposed as including PAs, NPs, CNSs, and CNMs. Several commenters expressed support for the proposed definition of “nonphysician practitioner,” and many others requested that we include additional types of NPPs within the scope of the exception. Among the NPPs that commenters suggested we include in the definition of “nonphysician practitioner” are physical therapists, CRNAs, registered dietitians, and nutritional professionals. As noted elsewhere, commenters that urged us to permit NPPs to furnish mental health services in addition to primary care services requested the corresponding inclusion of clinical social workers and clinical psychologists in the definition of “nonphysician practitioner.” In contrast, one commenter expressed concern regarding any expansion of the exception that would permit assistance to physicians to employ other nonphysicians, such as physical therapists.

In support of its recommended expansion of the definition to include registered dietitians and nutritional professionals, the commenter asserted that these professionals are an important part of the collaborative care system. With respect to expanding the definition of “nonphysician practitioner” to include CRNAs, a commenter noted that CRNAs may be licensed in their jurisdictions to furnish evaluation and management (E/M) services, as well as other services that would fit the proposed definition of primary care services, and that, because of this, elsewhere in the proposed rule CMS proposed to add CRNAs to the list of practitioners under section 1834(m)(4)(E) of the Act who may provide Medicare telehealth services. The commenter asserted that CMS should follow the same policy for CRNAs under the proposed exception at

§411.357(x). According to the commenter, CMS has proposed a range of safeguards which, when applied to NPPs, including CRNAs, should alleviate any concerns regarding risk of fraud and abuse. The commenters that supported the inclusion of physical therapists in the definition of “nonphysician practitioner” for the purposes of the new exception claimed that a substantial number of primary care practice patients have musculoskeletal complaints.

Response: Except with respect to clinical social workers and clinical psychologists, we decline to expand the definition of “nonphysician practitioner” as requested by the commenters. We continue to believe that PAs, NPs, CNSs, and CNMs are the types of NPPs who practice in the areas of general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology, which we consider to be primary care services. As discussed elsewhere in this section, we are finalizing the exception at §411.357(x) to permit remuneration to a physician who compensates an NPP to provide mental health care services to patients of the physician’s practice. Therefore, we are finalizing the exception to define NPP for the purposes of §411.357(x) as a PA (as defined in section 1861(aa)(5) of the Act), a NP or CNS (as defined in section 1861(aa)(5) of the Act), a certified nurse-midwife (as defined in section 1861(gg) of the Act), a clinical social worker (as defined in section 1861(hh) of the Act), or a clinical psychologist (as defined in §410.71(d)). The reasoning for this determination is set forth below.

Because we are not persuaded that registered dietitians or nutritional professionals provide the types of services we consider to be primary care services or mental health care services for the purposes of the exception, we do not believe that including registered dietitians or nutritional professionals in the definition of NPP would further the goals of increasing access to primary care services and mental health care services. Moreover, the commenters did not demonstrate a compelling need to include such practitioners in the definition of NPP for the purposes of the exception.

With respect to CRNAs, the commenter is correct that we proposed 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 may furnish Medicare telehealth services (80 FR 41784). 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 the purposes of furnishing Medicare telehealth services, the term “practitioner” has the meaning given that term in section 1842(b)(18)(C) of the Act, which includes a CRNA as defined in section 1861(bb)(2) of the Act. 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 services on the list of Medicare telehealth services, but now recognize that, in some States, CRNAs are licensed to furnish certain services on the telehealth list, including E/M services. Although we are finalizing our proposal to add CRNAs to the list of distant site practitioners for telehealth services in this final rule, we do not believe that it is necessary or appropriate to include CRNAs in the definition of NPP for the purposes of the exception to the physician self-referral law at §411.357(x).

Not all E/M services are primary care services. The commenter did not provide sufficient information for us to determine whether the “other services” which it claims CRNAs are licensed to furnish in certain States would qualify as general family practice, general internal medicine, pediatrics, geriatrics, or obstetrics and gynecology services. Moreover, although some CRNAs may be licensed to furnish some E/M services, we are not convinced that CRNAs generally furnish primary care services to the extent that the exception mandates. We are similarly not convinced that CRNAs would furnish mental health care services under the expanded exception finalized here. Therefore, we see no compelling need to include CRNAs in the definition of “nonphysician practitioner” for the purposes of the exception at §411.357(x).

We do not believe that physical therapists furnish primary care services or mental health care services to patients. The commenters suggested only that physical therapists may serve the needs of patients of a primary care practice, not that they furnish primary care services themselves. We do not find this a compelling reason to expand the scope of the exception to include physical therapists in the definition of “nonphysician practitioner.”

Comment: One commenter urged that we allow the employment of any NPP that would qualify as a primary care provider under the definition at §425.20 and §425.404, which pertain to accountable care organizations (ACOs) in the Shared Savings Program.

Response: Sections 425.20 and 425.404 relate to (1) definitions of a “primary care physician” (not an NPP) and “primary care services” (not providers) and (2) special assignment conditions for ACOs that include FQHCs and RHCs, respectively. The definition of “primary care services” at §425.20 includes a set of services identified by certain CPT, HCPCS and revenue center codes. We believe that the commenter is suggesting that we include in our definition of NPP for the purposes of new §411.357(x) any practitioner that furnishes services denoted by the codes that make up “primary care services” for the purposes of the Shared Savings Program. We decline to do so because we see no reason to condition compliance with the physician self-referral law on requirements of the Shared Savings Program. However, we note that the primary care “specialty designations” of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine that qualify a physician as a “primary care physician” for performance year 2016 under §425.20 align identically with the services we consider to be primary care services for the purposes of §411.357(x).

Comment: Two commenters urged CMS to identify PAs, NPs, CNSs, and CNMs by their properly earned credentials. The commenters stated that the use of the term “nonphysician practitioners” diminishes the value of these professions by identifying them in the negative.

Response: Our use of the term “nonphysician practitioner” is not intended to diminish the value of PAs, NPs, CNSs, certified nurse-midwives, or any other professional who provides services to Medicare beneficiaries. In the interest of clarity and to simplify compliance with the exception, we are retaining the term “nonphysician practitioner” to encompass the PAs, NPs, CNSs, CNMs, clinical social workers, and clinical psychologists that are covered by the exception.

Comment: Numerous commenters urged CMS to include independent contractors within the scope of the exception for NPP employment. One of the commenters noted that, especially in rural areas, primary care providers are usually recruited from urban areas as part-time independent contractors, as it can be difficult to attract such individuals as full-time members of the community. Commenters variously maintained that expanding the scope of the exception to independent contractor NPPs would promote flexibility, remove a barrier to attracting needed practitioners to underserved areas, and help insure increased availability of primary care services. Most commenters emphasized that the fact of an independent contractor relationship does not create or pose any greater potential for fraud and abuse than a standard employment relationship. One commenter noted that Medicare does not limit reassignment only to situations in which the physician organization has employed the NPP, and suggested that we should extend the scope of the exception to any arrangement that is lawful and will permit the physician organization to obtain payment for the services furnished by the NPP.

Response: We agree with the commenters that expanding the exception to permit a hospital, FQHC, or RHC to provide assistance to a physician to employ, contract with, or otherwise engage an NPP under a compensation arrangement to furnish primary care services or mental health care services to patients of the physician’s practice would support our underlying goal of increasing access to needed care. However, we do not believe that a contractual

relationship between a physician (or a physician organization in whose shoes the physician stands) and an NPP would necessarily result in the same nexus or level of accountability as an employment relationship between the parties. In order to safeguard against program or patient abuse that may arise in the absence of the close nexus between employer and employee, we are requiring that, where the NPP is an independent contractor, the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is directly between the physician (or a physician organization in whose shoes the physician stands under §411.354(c)) and the NPP. Accordingly, the exception finalized at §411.357(x) would permit both (1) a compensation arrangement between a physician and an NPP for employment and (2) a compensation arrangement directly between a physician and an NPP for contracted services. As noted previously, we refer to new §411.357(x) as an exception for assistance to compensate an NPP. An arrangement between a physician and a staffing company that has the direct contractual or employment arrangement with the NPP that provides services to patients of the physician's practice would not be permitted under the new exception.

Comment: One commenter requested that we expand the exception to permit assistance to recruit an NPP to become an owner of a physician practice. According to this commenter, given the increasing numbers of NPPs, primary care practices are “resorting to bringing in NPPs as owners” of the practices. The commenter also requested that, if we expand the exception to cover ownership interests within its scope, we establish a different cap on remuneration where the NPP joins the practice as an owner. The commenter did not specify what the “ownership” cap should be.

Response: We decline to adopt the commenter's suggestion. We are unclear whether the commenter is requesting that we establish an exception that permits a hospital, FQHC, or RHC to provide remuneration directly to an NPP to purchase an ownership interest in a physician

practice, or whether the commenter is requesting that we expand the scope of §411.357(x) to permit a hospital, FQHC, or RHC to reimburse a physician for amounts loaned to an NPP that purchases an ownership or investment interest in the physician's practice. As to the first alternative, as discussed above, a direct compensation arrangement between a DHS entity and an NPP does not implicate the physician self-referral law unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. However, such an arrangement may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act). As to the second alternative, we are not persuaded that facilitating ownership in a physician practice poses no risk of program or patient abuse.

Comment: Two commenters also urged us to expand the types of services listed as primary care services for the purposes of the exception to include mental health care services. In support of this request, one of the commenters stressed the well-documented, pressing need for mental health care in the United States and decreasing access to mental health care. A third commenter noted the compelling need for access to mental health care services, referencing a study indicating that up to 70 percent of primary care visits stem from psychosocial issues; that is, although patients may present with physical health complaints, underlying mental health or substance abuse frequently triggers these visits. The commenter stated that this problem is exacerbated by the fact that many communities have a critical shortage of providers to whom patients with mental health needs can be referred. The commenter cited in support of its recommendations, Collins, C., Hewson, D., Munger, R., Wade, T. (2010), "Evolving Models of Behavioral Health Integration in Primary Care (Milbank Memorial Fund)," August 29, 2015, available at <http://www.milbank.org/uploads/documents/10430EvolvingCare/EvolvingCare.pdf>.

Response: We agree with the commenters that there is a severe lack of access to mental health care services, and that the exception should be expanded to permit financial assistance for

the compensation of NPPs who furnish mental health care services. We are persuaded by the study cited by the commenter, as well several other studies and surveys showing a high demand for mental health care services and a substantial shortage of providers.

The demand for mental health services is considerable; one in every five adults will suffer from a mental illness or substance abuse disorder in a given year. In 2013, national surveyors found that 43.8 million adults in the United States (18.5 percent of the national population) had a mental illness during the year. (Substance Abuse and Mental Health Administration, *Results from the 2013 National Survey on Drug Use and Health*). Additionally, surveys indicate there are 12.3 million adults in the United States who have a substance abuse disorder without a concurrent mental illness. (Substance Abuse and Mental Health Administration, *Results from the 2014 National Survey on Drug Use and Health*).

A large portion of those suffering from mental illness are not receiving treatment. Of the adults suffering from a mental illness in 2013, only 19.6 million (44.7 percent) received mental health services. (2013 National Survey). One of the most significant barriers to care was a lack of mental health care professionals. In fact, 25.5 percent of those who were unable to receive services did not know where to go for help. (2013 National Survey). This is because, in many areas, there are few or no mental health care professionals available. Seventy-seven percent of counties in the United States have a severe shortage of mental health workers, and 55 percent of counties have no practicing psychiatrists, psychologists, or social workers. (Substance Abuse and Mental Health Services Administration, *Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*). In 2012, HRSA reported that there were 3,669 mental health care professional shortage areas that collectively contained 91 million people. (Report to Congress). This equates to a shortage of 1,846 psychiatrists and 5,931 NPPs. (Report to Congress). HRSA projects that by 2020, 16,624 child and adolescent psychologists will be

needed, but the expected supply is 8,312 (Report to Congress), and that between 2012 and 2025, overall demand will grow by 10 percent while supply will decline by 900 psychologists. (Health Resources and Service Administration, *Health Workforce Projections*, Psychologists).

We agree with the commenters that there is a compelling need for more mental health care professionals. We believe further that permitting hospitals, FQHCs, and RHCs to provide assistance to a physician to compensate NPPs to provide mental health care services to patients of the physician's practice may improve access to such critically needed services. In turn, we anticipate that increased access will promote treatment, improve outcomes, and may reduce the societal costs of mental illness. We are expanding the scope of the exception at §411.357(x) to permit an NPP for whom a physician receives assistance from a hospital, FQHC, or RHC to furnish mental health care services to patients of the physician's practice.

Comment: Some commenters urged CMS to broaden the exception to include arrangements under which the NPP furnishes any type of care because NPPs contribute to addressing specialty workforce shortages, particularly in underserved and rural areas, remove barriers to needed care, such as ongoing management of chronic conditions by specialists, and address important needs of beneficiaries, including increased access to care. One of these commenters suggested that, provided there is a demonstrated shortage of specialty providers and where additional availability of NPPs may help address the specialty care shortage concerns, payments made to a physician to employ an NPP to furnish specialty care services should be permissible. A different commenter urged us to expand the exception to all specialties because all specialties are feeling increased demand for services created by the Affordable Care Act.

Response: In the proposed rule, we solicited comments regarding whether there is a compelling need to expand the scope of the exception to NPPs who provide services that are not considered primary care services and, if so, safeguards that could be included to ensure no risk of

program or patient abuse (80 FR 41911). Other than the studies discussed in a separate comment and response regarding mental health care services, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. We do not believe that an increase in demand for specialty services necessarily correlates to a barrier to access to those specialty services. Although we appreciate the views of these commenters, without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, we are not inclined to adopt the revisions requested by the commenters. The exception at §411.357(x), as finalized here, is limited to NPPs who furnish primary care services or mental health care services.

Comment: Several commenters urged us to expand the scope of the exception to permit a hospital, FQHC, or RHC to provide remuneration to a physician to employ NPPs who practice in certain other specialties, including those who provide neurology, urology, cardiology, surgery, and orthopedic services. One commenter stated that there is an acute need for NPPs who provide neurology and urology services in many community hospitals and, further, that it is not unusual for a surgical practice or an anesthesia practice to have the same “compelling need” for a hospital’s assistance as does a primary care practice. Some commenters suggested that we permit the NPP to practice in any specialty. One commenter recommended that CMS ease the requirement on the services furnished by the NPP to include those non-primary care services for which the local jurisdiction licenses NPPs. A different commenter urged CMS to extend the scope of the proposed exception to remuneration provided to physicians who employ NPPs who provide cancer care, noting that such NPPs often provide enhanced primary care and care coordination services to many of their patients. Yet another commenter requested an equal

playing field for specialty and subspecialty physician organizations, stating that this would be a more straightforward way for CMS to encourage access to NPPs and the services that they provide as part of care teams.

Response: For the reasons described in the response to the previous comment, we decline to expand the scope of the exception to permit NPPs to furnish services other than primary care services or mental health care services to patients of the practice of the physician receiving the assistance from a hospital, FQHC, or RHC. Moreover, in our view, a physician practice's perceived need for financial assistance does not equate to or necessarily demonstrate a need for health care services in a geographic area. We note that nothing in §411.357(x) prohibits a hospital, FQHC, or RHC from providing remuneration to a specialty physician who compensates an NPP to furnish primary care services or mental health care services to patients of the physician's practice. We remind readers that the purpose of the exception as finalized is to remove barriers to care that may frustrate certain goals of health care delivery system reform and to promote beneficiary access to primary care services and mental health care services, not to promote access to the services of particular type of care provider (for example, an NPP).

Comment: One commenter expressed concerns with expanding the exception to permit the employment of NPPs who provide services other than primary care services, specifically raising concerns regarding physical therapy furnished by therapists employed by a physician or physician organization.

Response: We are expanding §411.357(x) only to the extent that the exception permits the a hospital, FQHC, or RHC to provide assistance to a physician to compensate an NPP who furnishes primary care services or mental health care services to patients of the physician's practice. As finalized, §411.357(x) would not protect assistance to a physician who compensates an NPP to furnish physical therapy services to patients of the physician's practice. As described

above, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. Without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, including physical therapy services, we are not inclined to adopt the revisions requested by the commenters.

Comment: Two commenters urged CMS to expand the exception to hospitals that provide remuneration to physicians providing specialty care who employ NPPs. One of these commenters suggested specifically that we expand the exception to permit the employment of NPPs who furnish only primary care services, but furnish such services to the patients of a specialty physician practice. The other commenter suggested that CMS should not use the physician self-referral regulations to support one particular specialty over another, and that an expansion poses no risk of program or patient abuse. Another commenter went so far as to state that it is an abuse of CMS's authority to extend the scope of the exception to only certain physician specialties.

Response: The exception is available to any physician who compensates an NPP to furnish primary care services or mental health services to patients of the physician's practice. The physician's specialty, even if it is not primary care or mental health care, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services.

Comment: One commenter sought confirmation that the exception would permit hospitals, FQHCs, and RHCs to provide remuneration to physicians who practice in hospital-based emergency departments. The commenter noted that such physicians provide enhanced

primary care and care coordination services to many of their patients, particularly those who present to the emergency department without a primary care provider or those who have limited access to community-based primary care providers. The commenter read our proposal to be limited to assistance to individual physicians.

Response: We understand the commenter to be questioning the availability of the exception for hospitals, FQHCs, and RHCs that wish to provide assistance to private physician practices that specialize in emergency medicine and furnish patient care services in hospital emergency departments. As such, we reiterate that the physician's specialty, even if it is emergency medicine, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services, and the arrangement must satisfy all of the requirements of the exception at §411.357(x).

Comment: One commenter urged us to interpret "primary care services" as broadly as possible because, as health care delivery shifts to patient-centered models of care, a greater diversity of services will be necessary to meet the needs of patients in the primary care setting. Other commenters urged us to broaden the definition of "primary care services" to include services furnished by allergists, immunologists, and rheumatologists.

Response: After careful consideration of these comments and the comments urging us to permit assistance to a physician to compensate an NPP who furnishes any type of services to patients of the physician's practice, we decline to consider any types of services other than those in our proposal to be "primary care services." General or family practice, general internal medicine, pediatrics, and obstetrics and gynecology are the four primary care specialties counted by the Health Resources and Services Administration (HRSA) when determining primary care health professional shortage areas (HPSAs). Further, geriatrics is considered an acceptable

primary care specialty under the Primary Care Loan program administered by HRSA. We note that nothing in this rule or the exception at §411.357(x) precludes a qualified professional, including an NPP, from furnishing general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services—which we consider “primary care services” for the purposes of §411.357(x)—regardless of the individual’s specialty training or designation.

Comment: One commenter suggested that the term “only primary care services” at proposed §411.357(x)(1)(vi)(B) could generate uncertainty and necessitate additional rulemaking. Another commenter understood “only primary care services” to mean that at least 75 percent of the services furnished by the NPP must be primary care services and found this requirement to be reasonable. Other commenters explicitly asked that we adopt a “substantially all” test for the primary care services furnished by the employed NPP, stating that this standard is most appropriate and consistent with other CMS regulations. Moreover, according to these commenters, a standard requiring that the NPP provide “only” primary care services could hamper the impact of the exception. We received no comments in support of a different standard for the minimum amount of primary care services that an NPP must furnish under the exception.

Response: Proposed §411.357(x)(1)(vi)(B) set forth a minimum amount of primary care services that must be furnished by the NPP for whose employment a physician receives assistance from a hospital, FQHC, or RHC, and stated that the NPP must provide “only” primary care services to patients of the physician practice. In our discussion of this requirement, we proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician’s practice by the NPP: (1) at least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services (80 FR 41911). We stated that we would define “substantially all” patient care services consistent with our

regulations at §411.352(d) and §411.356(c)(1); that is, at least 75 percent of the NPP's services to patients of the physician's practice must be primary care services.

We agree with the commenters that a "substantially all" standard is the appropriate standard for the minimum amount of primary care services or mental health care services that an NPP must furnish to patients of the physician's practice. Therefore, we are finalizing §411.57(x)(1)(vi) to require that substantially all of the patient care services furnished by the NPP must be primary care services or mental health care services. We expect that physician organizations that qualify as "group practices" are familiar with this standard, as are rural providers. As we have throughout the physician self-referral regulations, we are defining "substantially all" patient care services to mean at least 75 percent of the NPP's services to patients of the physician's practice. To ensure consistency in the interpretation of identical terms used in our regulations, we are requiring that "patient care services" be measured by one of the following: (1) the total time the NPP spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries); or (2) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented. See §411.352(d)(1). For clarity, we are including this requirement in §411.357(x) as finalized in this final rule.

Comment: Two commenters urged us to adopt only the bright-line test of 50 percent of the actual salary, signing bonus, and benefits paid to the NPP as the limit on the amount of remuneration that a hospital, FQHC, or RHC may provide to a physician to employ an NPP. One of these commenters suggested that the remuneration methodology should be as simple and straightforward as possible, and that the final rule should avoid complicating the exception and exposing hospitals to noncompliance due to incomplete or inaccurate documentation related to

receipts for the NPP's services to patients of the physician's practice. Another commenter urged us to permit hospitals to utilize either method of determining the maximum amount of permissible assistance set forth at §411.357(x)(1)(iii), without regard to which results in the lower amount of remuneration from the hospital, FQHC, or RHC to the physician. The commenter stated that the "payments less receipts" methodology (with payments equal to the salary, signing bonus, and benefits paid to the NPP) is speculative at the outset of the compensation arrangement and cannot be determined with certainty at that time to be lower than 50 percent of the actual salary, signing bonus, and benefits paid to the NPP by the physician or physician organization. The commenter also raised the complicating issue of nonphysician services billed incident to a physician's service rather than under the NPI assigned to the NPP. Moreover, having a "lower of" standard effectively requires parties to use both methodologies to determine which results in the lower amount of remuneration, even if only one is desired. To avoid "after-the-fact" violations of the physician self-referral law, the commenter suggested that hospitals, FQHCs, and RHCs should be given the choice of selecting either of these two methodologies for determining the amount of assistance they will provide to the physician or physician organization.

Response: We agree with the commenters that recommended establishing a clear, objective standard for determining the maximum amount of assistance that a hospital, FQHC, or RHC may provide to a physician would best serve the interests of hospitals, FQHCs, and RHCs that provide assistance to a physician to compensate an NPP. Such a standard would serve to facilitate compliance with the physician self-referral law, which is a primary purpose of certain of these updates to our regulations. Upon further consideration of the "receipts minus salary, signing bonus, and benefits" methodology, we are abandoning this option in favor of a bright-line approach that permits a hospital, FQHC, or RHC to provide assistance to a physician in an

amount that does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP who joins the physician's practice. We 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. As we stated in the proposed rule, we recognize that compensation 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 finalizing 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 NPP's salary, signing bonus, and benefits be set in advance.

We recognize the challenges posed by a standard under which a hospital's, FQHC's, or RHC's compliance with the law depends on precise determinations of which services are "attributable" to an NPP, adequate record keeping of the physician, and the cooperation of the physician in sharing information regarding the receipts for services furnished by the NPP's services. Compliance challenges would be exacerbated where the NPP furnishes services that are incident to a physician's service and billed under the name (or NPI) of the physician. The third commenter's recommended approach of an "either/or" standard, rather than a "lower of" standard, while providing flexibility to hospitals, FQHCs, and RHCs, does not alleviate the significant compliance challenges posed by the "receipts minus salary, signing bonus, and benefits" standard, and we are not adopting it. We note that our goal in establishing the exception at §411.357(x) is to expand access to critically needed primary care services and mental health care services. The exception is not intended to provide a physician with the means to increase profit from the services of an NPP in his or her practice at the expense of a hospital,

FQHC, or RHC. We intend to monitor the use and impact of the exception for potential program or patient abuse.

Comment: One commenter requested that we increase the limit on the amount of salary, signing bonus and benefits for which a hospital, FQHC, or RHC may provide assistance. The commenter stated that 60 percent would be a more appropriate cap, as that percentage is more closely aligned with added overhead associated with adding an NPP to a physician practice. The commenter provided no data to support this statement. Another commenter recommended that we permit remuneration to a physician to cover the cost of the NPP's relocation. This commenter suggested that a hospital, FQHC, or RHC should be permitted to cover such costs if the NPP was located outside the geographic area served by the hospital and moves at least 25 miles to join the physician practice, as measured from the physician practice's primary place of business (or, if multiple locations, the location where the NPP will primarily practice). The commenter did not specify whether the previous location of the NPP refers to his or her practice location or whether remuneration to cover relocation costs should be subject to the overall cap on remuneration provided under the exception.

Response: Nothing in the exception at §411.357(x) prohibits a hospital, FQHC, or RHC from providing assistance to a physician that includes an amount associated with the relocation costs of the NPP joining the physician's practice, provided that: (1) the amount is included when calculating the aggregate compensation from the physician to the NPP; (2) the assistance from the hospital, FQHC, or RHC does not exceed the cap established at §411.357(x)(1)(iii)(A); and (3) the compensation to the NPP—including any amount associated with the relocation costs—does not exceed fair market value for the patient care services furnished by the NPP to patients of the physician's practice. In other words, the hospital, FQHC, or RHC may provide remuneration to the physician to cover relocation costs of the nonphysician provider if the

relocation costs are included in the calculation of the actual aggregate compensation, signing bonus, and benefits paid by the physician to the NPP, and all other requirements of the exception are satisfied.

Comment: One commenter recommended that we replace the cap on remuneration in proposed §411.357(x)(1)(iii)(A) with the analogous safeguards in the exception for physician recruitment, namely a limitation on remuneration not to exceed the actual additional incremental costs attributed to the NPP. The commenter claimed that doing so would serve the same goal of limiting any windfall to the physician while having the advantage of administrative simplicity. Another commenter stated that it failed to see any rationale for limiting assistance to only a portion of the additional incremental costs attributable to the NPP, such as 50 percent of the actual salary, signing bonus, and benefits as set forth in proposed §411.357(x)(1)(iii)(A), and suggested that assistance should be limited to “no more than” the actual additional incremental costs attributable to the employed NPP (that is, 100 percent of the actual incremental costs attributable to the NPP). The commenter stated in support that hospitals have experience in using this methodology, but recognized that it could be difficult to determine amounts under an income guarantee if the NPP’s services were billed incident to a physician’s service.

Response: We decline to adopt a standard that would potentially permit a hospital, FQHC, or RHC to cover 100 percent of the costs attributable to adding an NPP to a physician’s practice and thus result in a windfall to the physician. We stated in the proposed rule and continue to believe that hospitals, FQHCs, or RHCs should not bear the full costs of employing (or otherwise compensating) NPPs who work in private physician practices (80 FR 41912). We are establishing the exception at §411.357(x) using the Secretary’s authority in section 1877(b)(4) of the Act, which allows exceptions only for those financial relationships that do not pose a risk of program or patient abuse. Permitting a physician to shift unlimited overhead costs

to the hospital, FQHC, or RHC to which he or she refers may pose a risk of program or patient abuse. Moreover, the methodology advocated by the commenters would not further our goal of facilitating compliance and reducing complexity in our regulations.

Comment: One commenter requested that we increase the permissible period for assistance from 2 years to 3 years, noting that it may require more than 2 years for an NPP's practice to develop and for the physician organization to break even on the NPP's employment. The commenter gave the example of a CNM whose services are often not paid for until the baby is delivered, resulting in a lengthy period until his or her practice develops and for the physician organization to realize the revenue for the CNM's services. Another commenter recommended that we expand the permissible period for assistance to at least 3 years, which, in the commenter's view, will help achieve the policy goals of reducing workforce shortages and increasing access to quality care. The commenter stated that adding an additional year to the permissible period of assistance poses no risk of program or patient abuse.

Response: The purpose of the exception at §411.357(x) is not to permit a hospital, FQHC, or RHC to subsidize a physician until the physician "breaks even" or earns a profit on the NPP's employment or contract. Rather, the exception is intended to promote beneficiary access to care and support the goals of health care delivery and payment system reform. As we stated in the proposed rule, we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP employment (or contracting) and other practice costs (80 FR 41911). As discussed elsewhere in this section, we are finalizing a 3-year limitation on the frequency of a hospital's, FQHC's, or RHC's use of the exception for a particular physician. In light of this, we believe that the 2-year limit on assistance to employ or contract with an NPP is necessary to prevent the program or patient abuse that may result from ongoing or permanent subsidies of a physician's NPP employment (or contracting) and other practice costs. A 3-year

limit on assistance effectively would permit permanent subsidies of physician practices. As we noted in the proposed rule, ongoing or permanent subsidies could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC providing the assistance (80 FR 41912). We disagree with the commenter that stated that adding an additional year to the permissible period of assistance would not pose a risk of program or patient abuse.

Comment: One commenter supported the safeguards we proposed for the new exception, noting that they are appropriate to prevent abuse. The commenter endorsed a limit on the number of times a hospital, FQHC or RHC may assist the same physician with the employment of a nonphysician, noting that once every 3 years is reasonable and consistent with other physician self-referral regulations, but requested that CMS include a waiver of the frequency limit in the event the NPP remains employed by the physician or his or her physician organization for less than 1 year. Another commenter requested that, if we impose a limitation on the frequency of the use of the exception, we include an exception for situations where an NPP leaves his or her employment or otherwise ceases to meet the requirements of the exception. The commenter did not suggest an appropriate time limitation for the NPP's departure from the physician practice. In contrast, two commenters submitted that the general safeguards proposed for the exception are sufficient and that additional safeguards would unnecessarily restrict the usefulness or availability of the exception. One of these commenters stated that physicians will not hire NPPs unnecessarily if doing so will result in a financial loss to the practice. The other of these commenters suggested that a limitation on the frequency or aggregate use of the exception for a particular referring physician is inconsistent with the exception for recruitment of a physician. Another commenter stated that a frequency limitation could potentially undermine

the goal of increased access to primary care and also considered it unnecessary to limit the number of times a hospital, FQHC, or RHC may assist the same physician.

Response: We understand the commenters' concerns that a frequency limitation could serve to undermine the goal of increased access to primary care services and mental health care services, but we are not convinced that omitting this safeguard would pose no risk of program or patient abuse. As discussed in response to other comments in this final rule, we believe that ongoing or permanent subsidies of a physician's NPP and other practice costs, which could occur in the absence of a limitation on the number of times a hospital, FQHC, or RHC may assist the same physician, may serve as an inducement to continue making referrals to the hospital, FQHC, or RHC and pose a risk of program or patient abuse. Therefore, we are finalizing a requirement in the new exception that limits the use of the exception for a particular physician to once every 3 years. However, we agree that the goal of increased access to primary care services and mental health care services could be undermined if this limitation prevented a physician from replacing an NPP who left the physician's practice after only a short time. To address this, we are making an exception to the frequency limitation finalized at §411.357(x)(8) to permit a hospital, FQHC, or RHC to provide assistance to a physician more than once every 3 years in the event that an NPP for whom the physician received assistance (the original NPP) did not remain with the physician's practice for 1 year or more. The 3-year period would begin on the date the hospital, FQHC, or RHC initially provided remuneration to the physician (to compensate the original NPP). Under final §411.357(x)(8), the hospital, FQHC, or RHC may provide assistance to the physician to compensate a second (or subsequent) NPP, provided that: (1) the aggregate remuneration from the hospital, FQHC, or RHC does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the replacement NPP; and (2) the assistance is limited to the consecutive 2-year period that begins on the date the original NPP

commenced employment or a contractual arrangement with the physician (or physician organization in whose shoes the physician stands under §411.354(c)).

Comment: One commenter opposed an aggregate limitation on the number of times any individual physician could receive assistance. The commenter gave the example of a physician with a long-term career in a single geographic service area and noted that an absolute limit on the use of the exception vis-à-vis this physician could result in failure to meet CMS's goal of facilitating a meaningful increase in access to primary care.

Response: We are not finalizing an aggregate limit on the number of times a hospital, FQHC, or RHC may provide assistance to the same physician to compensate an NPP to furnish primary care services or mental health services to patients of the physician's practice.

Comment: One commenter referred to the limitation on the availability of the exception to situations where the NPP was not employed or otherwise engaged to provide patient care services in the geographic area served by the hospital, FQHC, or RHC for at least 3 years prior to the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician as the "disqualification" period. The commenter expressed its belief that a 3-year disqualification period is too restrictive and urged CMS to reduce the time period for "disqualification" to 1 year. For the same reason, the commenter urged CMS to remove the limitation on employing an NPP who has been employed or otherwise engaged by a physician practice that maintains a medical practice site within the geographic area served by the hospital, FQHC, or RHC, even if the NPP has not provided patient care services at that practice site (or sites). The commenter stated that both of these provisions restrict the mobility of NPPs and will decrease the effectiveness of the exception.

Response: The underlying purpose of the exception is to increase access to primary care services and mental health care services while removing barriers that could frustrate the goals of

health care delivery and payment system reform. Although we do not wish to restrict the mobility of NPPs, we are not convinced that we should remove from the exception important requirements that guard against program or patient abuse. We believe that prohibiting assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP who already furnishes patient care services in the geographic area served by the hospital, FQHC, or RHC (or furnishes patient care services to patients of a physician practice that has a medical office site located in the geographic area served by the hospital, FQHC, or RHC) is necessary to guard against shifting the long-term costs of employing and contracting with NPPs from private physician practices to hospitals, FQHCs, and RHCs.

However, we agree that a 3-year “disqualification” period could undermine the important goals of the exception and are finalizing §411.357(x)(1)(v) to include a 1-year limitation on the NPP’s prior practice in the geographic area served by the hospital, FQHC, or RHC. As finalized, the exception would not be available unless the NPP, within 1 year of being compensated by the physician (or the physician organization in whose shoes the physician stands under §411.354(c)): (1) has not practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance; and (2) has not been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC. We believe that a 1-year “disqualification” period (to use the commenter’s terminology) will serve adequately to prevent gaming by rotating or cycling NPPs through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC. Similarly, retaining the requirement that the NPP may not have been employed or otherwise engaged to provide patient care services by a physician or physician organization

that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance for at least 1 year prior to the remuneration to the physician, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC, will serve to prevent physicians from shifting the cost of currently employed NPPs to hospitals, FQHCs, and RHCs. In addition, these limitations may serve to protect against potentially competitive practices, such as a physician luring an NPP from another physician practice using hospital funding.

Comment: Two commenters requested that we include relief in the exception at §411.357(x) similar to that at §411.357(e)(3). According to one of these commenters, such an exception to the “geographic” requirement would allow a physician or physician practice to employ an NPP who was: (1) immediately prior to the employment, in training or in practice for less than 1 year; or (2) employed on a full-time basis by a Federal or State entity for at least 2 years immediately prior to the employment. The commenter stated that such a provision would expand the pool from which NPPs could be recruited and open up employment opportunities for NPPs who are either transitioning to private practice or beginning their careers without creating a risk of program or patient abuse. The other commenter also requested that, to recognize that unique circumstances could exist that support the availability of assistance in special cases, we provide in the exception for a waiver of the “geographic” requirement and the “temporal” requirement (that is, the 3-year “disqualification” period) if the Secretary determines in an advisory opinion that the area has a demonstrated need for the NPP.

Response: We decline to adopt the commenters’ recommendations. We believe the exception as finalized is sufficiently flexible to achieve its purpose. Although it may benefit NPPs in the way the first commenter suggested, the purpose of the exception at §411.357(x) is

not to facilitate opportunities for NPPs, but rather to increase access to primary care services and mental health care services.

Comment: One commenter urged us not to limit the exception to rural or underserved areas, because providers other than those in rural areas are experiencing shortages. We received no comments in support of limiting the use of the exception to hospitals, FQHCs, and RHCs located in rural or underserved areas.

Response: We did not propose to limit the availability of the exception to hospitals, FQHCs, and RHCs that provide assistance to physicians who compensate NPPs to furnish services only in rural or underserved areas. We are not finalizing such a limitation.

Comment: One commenter suggested that CMS make clear that the definition of “referral” in proposed §411.357(x) applies only to the exception for hospital assistance to a physician to employ an NPP, and not to the physician self-referral regulations in their entirety.

Response: As we explained in the proposed rule, the definition of “referral” at §411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician (80 FR 41912). This term is used throughout our regulations and is applicable when used in reference to the referrals of a physician. Our regulations currently do not include a term that references the request, ordering of, or certifying or recertifying the need for DHS by an NPP. For this reason, solely for the purposes of the requirements of the new exception, we proposed to define the term “referral,” as it relates to NPPs, as a request by an NPP that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by an NPP 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 NPP. We are finalizing this definition at §411.357(x)(4).

Summary of the provisions in the exception for assistance to compensate an NPP, as finalized at §411.357(x)

After careful consideration of the comments regarding the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP, we are finalizing our proposed exception at §411.357(x) with the following modifications: (1) we are including in the definition of “nonphysician practitioner,” for the purposes of the exception at §411.357(x) clinical social workers and clinical psychologists; (2) we are expanding the type of services that may be furnished by the NPP to patients of the physician’s practice to include mental health care services; (3) we are including a requirement that the NPP furnish substantially all primary care services or mental health services (rather than “only” such services) to patients of the physician’s practice; (4) we are not limiting the type of compensation arrangement between the physician (or physician organization in whose shoes the physician stands) and the NPP, but we are requiring that the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is directly between the physician (or a physician organization in whose shoes the physician stands under §411.354(c)) and the NPP; (5) we are establishing a bright-line approach to the amount of permissible remuneration from the hospital, FQHC, or RHC to the physician, limiting it to 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP; (6) we are finalizing a limit on the frequency with which a hospital, FQHC, or RHC may provide assistance to the same physician and setting the limitation at no more than once every 3 years, with an exception if the NPP does not remain with the physician’s practice for at least 1 year; and (7) we are shortening from 3 years to 1 year the period of time that the NPP must not have practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance.

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 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 and Phase III, we expanded the exception to FQHCs and RHCs, respectively, and revised the definitions of "geographic area served by a hospital." As we explained at 80 FR 41913, the definition of "geographic area served by a hospital" adopted in Phase III does not provide guidance as to the geographic area into which an FQHC or RHC may recruit a physician, a concept critical for compliance with the exception's requirements. Therefore, we proposed to revise §411.357(e)(6) to add a new definition of the geographic area served by an FQHC or RHC.

We proposed two alternative approaches for this policy, which aligns closely with the special optional rule for rural hospitals at §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 to achieve their goals of providing needed services to the communities that they serve. The first proposed approach closely mirrors our current definition of a rural hospital's geographic service area. It would define the geographic area served by an FQHC or RHC as 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. Under our first proposal, 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 could 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 could 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 proposed to define the geographic area served by an 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. We solicited comments on each of these alternatives, including whether patient encounters is the appropriate measure for determining the geographic area served by an FQHC or RHC. Finally, we solicited 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.

We are finalizing our proposal to define, for the purposes of the exception at §411.357(e), the geographic area served by an FQHC or RHC as 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. The following is summary of the comments we received.

Comment: Several commenters recommended that CMS use the definition for geographic area served by an FQHC or RHC that does not use contiguity as a factor. These commenters noted that the prior lack of clarity regarding the area into which a physician recruited by an FQHC or RHC must move his or her medical practice may have deterred such entities from making recruitment payments to attract physicians to underserved areas. Another commenter noted concurrence with our proposed approach to defining the geographic area served by an FQHC or RHC, but requested that we allow the FQHC or RHC to include one or more zip codes from which the entity 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. According to the commenter, this would allow an FQHC or RHC to take into account potential patients. The commenter also suggested that we determine service areas based on patients rather than encounters, but gave no reason why this measure would be more appropriate than encounters. A different commenter agreed that patient encounters are the appropriate measure for determining the geographic area served by an FQHC or RHC.

Response: We are finalizing our alternative proposal to define the “geographic area served” by an 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. As stated in the proposed rule, 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 (80 FR 41913). Also, under this final rule, the FQHC or RHC is permitted to include one or more zip codes from which the FQHC or RHC draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients. Hospitals that provide recruitment assistance to physicians are provided this flexibility under §411.357(e)(2)(i). As described at §411.357(e)(6), the exception applies to remuneration provided by an FQHC or RHC in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the Federal anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. We see no risk of program or patient abuse in extending the ability to include “hole” zip codes (as we described them in Phase III (72 FR 51050)) to FQHCs and RHCs when determining the geographic areas that they serve. We are not persuaded that “patients” is a more appropriate measure than “encounters” for determining service areas, and are not adopting the

change recommended by the commenter who suggested that we determine the geographic area served by an FQHC or RHC based on patients of the FQHC or RHC.

Comment: In response to our solicitation of comments regarding whether the exception at §411.357(e) for physician recruitment is useful to FQHCs and RHCs, several commenters noted that, in their experience, the existing exception is not widely known or used. The commenters encouraged CMS to better publicize the exception to the rural health community so that it may take advantage of this recruitment tool. Another commenter stated that the exception is of limited utility to FQHCs because, as safety net providers, FQHCs struggle to pay market salaries to attract clinicians, and incentive payments are often financially infeasible for FQHCs.

Response: We appreciate the input of the commenters and will consider ways to provide better outreach to FQHCs and RHCs regarding the physician self-referral law and its exceptions.

After careful consideration of the comments, we are finalizing our proposal to define the geographic area served by an FQHC or RHC, for the purposes of the exception at §411.357(e), as 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. We are also permitting FQHCs and RHCs to include one or more zip codes from which they draw no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients, determined on an encounter basis.

c. Conforming Terminology: “Takes into Account”

Several exceptions for compensation arrangements in section 1877(e) of the Act 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).) As we explained in the proposed rule (80 FR 41914), our longstanding policy is to interpret the volume or value standard in all provisions under section 1877(e) of the Act uniformly.

Despite our uniform interpretation of the volume or value standard, the phrase “takes into account” is not used consistently in the exceptions for compensation arrangements in §411.357. 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) and §411.357(s) 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. See 80 FR 41914. To clarify the regulations, we proposed to modify §411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, we proposed 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 proposed to amend §411.357(r) to require that the amount of payment under the arrangement may not take into account the volume or value of any actual or anticipated referrals. Lastly, we proposed to revise the language of §411.357(m) and (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.

The following is a summary of the comments we received.

Comment: We received several comments supporting our proposal to consistently and uniformly use the phrase "takes into account" in reference to the volume or value standard in the exceptions for compensation arrangements in §411.357. One commenter asked CMS to distinguish between compensation that "varies with" the volume or referrals and compensation that "takes into account" the volume or value of referrals. Another commenter asked CMS to include in the regulations at §411.351 a definition of the phrase "takes into account."

Response: We are finalizing our proposal to make the use of the phrase "takes into account" consistent and uniform throughout the compensation arrangement exceptions in §411.357. We did not propose to define the term "takes into account," and we decline to do so at

this time. Nevertheless, we are considering the commenter's proposed definition of "takes into account" and related discussion as part of our solicitation of comments on the perceived need for clarification regarding permissible physician compensation. Likewise, we decline to discuss the meaning of the phrase "takes into account" in relation to the phrase "varies with," but we will consider the commenter's discussion of the issue as part of our solicitation of comments on permissible physician compensation.

As a result of the comments, we are finalizing the proposed changes to the regulations at §411.357(e), (m), (r), and (s). The revision of the regulatory language reflects our policy that the volume or value standard is uniform and consistent in the exceptions for compensation arrangements in §411.357.

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, FQHC, or RHC 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 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, to avoid confusion due to conflicting regulation text, we proposed to modify our regulations at §411.357(t)(2)(iv)(A) to reflect the regulatory intent we articulated in Phase III. The following is a summary of the comments we received.

Comment: We received one comment supporting our proposed regulatory change to §411.357(t). However, the commenter also stated that the current exception is too narrow, and urged CMS to expand the exception to permit retention payments as long as the hospital has a good faith belief that the physician is considering relocating his or her practice.

Response: We appreciate the commenter’s support, and we are finalizing the proposed revision of §411.357(t). We are not making any other changes to the exception at this time.

After reviewing the comments, we are finalizing our proposal to modify our regulations at §411.357(t)(2)(iv)(A). The revised regulatory text clearly states our intention, as formulated in Phase III, that entities contemplating retention payments must consider the entire 24-month period prior to the payment.

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 requirement 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 final rule with comment period clarifies the writing requirement 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 requirements in many exceptions. In addition, to reduce regulatory burden, we proposed to except certain holdover arrangements, provided that certain safeguards are met.

a. The Writing Requirement 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 (b)) require that a lease be set out in writing. Several other compensation exceptions have a similar writing requirement: 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) 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 section 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 (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. (For a similar discussion regarding arrangements among components of an academic medical center, see Phase II (69 FR 16110).)

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 at §411.357(a)(1) and (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 proposed to substitute the term “lease arrangement” for the term “agreement” at §411.357(a)(1) and (b)(1). We believe that this revision underscores the fact that the writing requirement at §411.357(a)(1) and (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 proposed 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).

In light of our proposal to clarify the writing requirement at §411.354(d)(1), (d)(4)(i), (a)(1), (b)(1), (e)(4)(i), and (l)(1) by removing the term “agreement,” we proposed to make conforming changes where possible to other provisions in the compensation exceptions and the special rules on compensation. Specifically, we proposed to replace the term “agreement” with the term “lease arrangement” in §411.357(a)(2), (a)(4), (a)(5), (a)(6), (b)(3), (b)(4), and (b)(5). We proposed to replace the term “agreement” with the term “arrangement” in §411.357(c)(3) (the exception for bona fide employment relationships) and §411.357(f)(2) (exception for isolated transactions). Likewise, we proposed 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 proposed to revise §411.354(d)(4) by replacing the word “contract” as it relates to personal service arrangements with the word “arrangement,” and we proposed similar changes to §411.357(e)(1)(iv) and (r)(2)(v), both of which refer back to §411.354(d)(4). We proposed 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 proposed 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 did not propose 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 (w) are aligned with the Federal anti-kickback statute safe harbors at §1001.952(x) and (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 (w). However, we believe that the principles elucidated above regarding the writing requirement of the other compensation exceptions to the physician self-referral law also apply to §411.357(v) and (w).

We are finalizing the proposed changes to clarify that parties need not reduce the key terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at §411.357 that require a writing. The following is a summary of the comments we received.

Comment: All the commenters addressing this issue supported our statement in the preamble that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of various compensation exceptions. Two commenters complained that the writing and signature requirements, when interpreted narrowly, elevate form over substance. Several commenters requested that CMS confirm that our statement regarding a collection of documents is a clarification of existing policy, and that parties need not self-disclose arrangements where the writing requirement was satisfied by multiple documents (and all other requirements of the

applicable exception were satisfied), even if the conduct occurred prior to the finalization of this rule.

Response: CMS' existing policy is that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the exceptions for compensation arrangements that require a writing. Our proposal to substitute the word "arrangement" for "agreement" throughout the exceptions for compensation arrangements was intended to clarify and confirm this existing policy regarding the writing requirement. Parties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine whether the party complied with the writing requirement of an applicable exception. To determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made.

Comment: Some commenters stated that State law contract principles should determine what constitutes an arrangement "set out in writing" for the purposes of the physician self-referral law. The commenters stated that health care providers and suppliers typically rely on State law principles to determine the validity and enforceability of written agreements, and that it would reduce the burden on providers and suppliers to use the same principles to determine compliance with the physician self-referral law.

Response: We decline to adopt the commenters' recommendation that State contract law principles should determine what constitutes an arrangement that is "set out in writing" for the purposes of the physician self-referral law. We are concerned that reliance on State contract law would result in different standards for compliance for different States and territories. In addition,

the requirements for a contract to be valid and enforceable under State law may differ substantively from the requirements of the physician self-referral law. For example, in certain instances, a short term service contract may be valid and enforceable under State law even if the agreement is not reduced to writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at §411.357(l), the arrangement would have to be set out in writing to satisfy the requirements of the exception. Similarly, a contract for the provision of items may be enforceable under State law even if the price for the items is not in writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at §411.357(l), the price of the items would have to be in writing to satisfy the requirements of the exception. Finally, we believe that it may be possible in some instances that writings documenting an arrangement may satisfy the writing requirement of the physician self-referral law, yet not form an enforceable contract under State law. In this context, we are concerned that reliance on State law contract principles may unduly narrow the scope of permissible arrangements under the physician self-referral law.

Although State law contract principles do not definitively determine compliance with the writing requirement of the physician self-referral law, the physician self-referral law does not negate or preempt State contract law. (See 72 FR 51049). Nothing prevents a party from drawing on State law contract principles, as well as other bodies of relevant law, to inform the analysis of whether an arrangement is set out in writing. The important point is this: what determines compliance with the writing requirement of the physician self-referral law is not whether the writings form a valid and enforceable contract under State law, but rather whether the contemporaneous writings would permit a reasonable person to verify that the arrangement complied with an applicable exception at the time a referral is made. For this reason, a written contract that is enforceable under State law may not satisfy the writing requirement if the actual

arrangement differed in material respects from the terms and conditions of the written contract.

Comment: Two commenters pointed out that the preamble discussion of the writing requirement did not address the corresponding signature requirement in various compensation arrangement exceptions. The commenters noted that the “collection of documents” that may satisfy the writing requirement would still have to be signed by the parties for the arrangement to comply with the applicable exception. The commenter indicated that it is not clear to the commenter what is required to satisfy the signature requirement when parties are relying on a collection of documents to satisfy the writing requirement. Two commenters requested confirmation that a party’s signature need only be included on one of the documents in the collection. Another commenter suggested that we draw on State law principles to clarify what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As explained elsewhere in this section, we do not believe that State law principles determine compliance with the physician self-referral law, including compliance with the signature requirement. Regarding the signature requirement as it relates to a collection of documents, we note that the proposed rule clarified that a single written contract is not necessary to satisfy the writing requirement of an applicable exception. We substituted the word “arrangement” for “agreement” in the compensation exceptions to underscore the fact that it is the arrangement (that is, the underlying financial relationship between the parties) that must be set out in writing; there is no requirement that this writing take the form a formal contract between the parties. Likewise, under the proposed rule—which is a clarification of our existing policy—it is the arrangement that must be signed by the parties to satisfy the exception. (See, for example, the proposed language for §411.357(a)(1) (“The lease arrangement ... is signed by the parties”). For the same reason that parties do not need a single formal written contract to comply with the writing requirement, parties also do not need to sign a *single* formal written

contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.

Comment: Some commenters asked for concrete examples of the kinds of documents (other than formal written agreements) that may satisfy the writing requirement of various compensation exceptions. In addition, one commenter specifically requested that CMS recognize that electronic documents, such as e-mail communications, may be used to satisfy the writing requirement.

Response: Because compliance with the writing requirement is fact-specific, we decline to give an example of a collection of documents that would, taken as a whole, satisfy the writing requirement. However, we are providing some examples of individual documents that a party might consider as part of a collection of documents when determining whether a compensation arrangement complied with the writing requirement of an applicable exception: board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent. This list of examples is not exhaustive, and we emphasize that, depending on the facts and circumstances, a party could have documents of each

type listed and nevertheless not satisfy the writing requirement of an applicable exception.

Among other things, the documents must clearly relate to one another and evidence one and the same arrangement between the parties.

Comment: One commenter stated that parties should be permitted a 60- or 90-day grace period for satisfying the writing requirement of various compensation exceptions. The commenter stated that such a grace period is needed for last minute arrangements between physicians and DHS entities.

Response: We decline to adopt the commenter's suggestion. A grace period for the writing requirement would not incent parties to document the terms and conditions of the arrangement promptly. For this reason, we believe that a grace period for the writing requirement poses a risk of program or patient abuse. For example, to the extent that the rate of compensation is not documented before a physician provides services to a DHS entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals. In this context, we note that the special rule at §411.353(g)(1) for temporary noncompliance applies only to noncompliance with the signature requirement of an applicable exception. All other elements of an applicable exception, including the applicable writing requirement, must be satisfied once a compensation arrangement between the parties is established (that is, as soon as items, services, or compensation under the arrangement passes between the parties) and the physician makes referrals to the DHS entity.

We remind parties that DHS entities have the burden of proof to establish that services were not furnished as a result of prohibited referrals, and that all requirements of an exception must be met at the time a referral is made. (See §411.353(c)(2)(i) and 73 FR 48703.) If an arrangement with a physician fails to comply with the writing requirement of an applicable

exception when the arrangement commences, then the entity is not permitted to bill for DHS furnished as a result of the physician's referrals unless and until the arrangement is sufficiently documented over the course of the arrangement (and all other requirements of the applicable exception are met). Contemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents. Likewise, parties cannot meet the set in advance requirement from the inception of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began; however, depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made after the contemporaneous documents are created. We reiterate that the surest and most straightforward means of complying with the writing requirement of the physician self-referral law is to reduce the key facts of an arrangement to a single signed writing before either party provides items, services, space, or compensation to the other party under the arrangement.

After careful consideration of the comments, we are finalizing our proposal to substitute the word "arrangement" for "agreement" in various provisions of §411.354 and §411.357 identified in the proposed rule. The revision of the regulatory language reflects our existing policy that a single formal contract is not required to satisfy the writing requirement of those compensation exceptions at §411.357 that require a writing.

b. Term Requirements in Certain Compensation Arrangements Exceptions

The exceptions at §411.357(a), (b), and (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 proposed to revise §411.357(a)(2), (b)(3), and (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, respectively, require that the lease arrangement 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 (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 section, we interpreted “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” at §411.357(a)(2) and (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), (b)(3), and (d)(1)(iv), as applicable. As is the case with the writing requirement in these and other exceptions, 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, 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 (b)(3), we proposed 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).

We are finalizing revised regulatory language that clearly reflects the policy stated in the proposed rule, namely that an arrangement need only last at least 1 year as a matter of fact to satisfy the 1-year term requirement at §411.357(a)(2), (b)(3), and (d)(1)(iv). The following is a summary of the comments we received.

Comment: All those that commented on this issue (38, 50, 68, 73, 80) supported our statement in the preamble that arrangements that last for at least 1 year satisfy the 1-year term requirement. One commenter requested that CMS confirm that the statement in the preamble regarding the 1-year requirement is a clarification of existing law. Another commenter (38) recommended that CMS further revise the regulatory language at §411.357(a)(2), (b)(3), and (d)(1)(iv), to make it more clear that arrangements need only last as a matter of fact for at least 1 year satisfy the 1-year requirement.

Response: To clarify that the length of an arrangement need not be stated explicitly in a

formal contract, we proposed to revise the 1-year term provisions at §411.357(a)(2), (b)(3), and (d)(1)(iv), by substituting the word “arrangement” for the word “agreement.” In the preamble, we explained that an arrangement that lasts as a matter of fact for at least 1 year would satisfy this requirement. We agree with the commenter that the proposed regulatory language does not unambiguously express our intent, as it was stated in the preamble. Specifically, we believe the word “term” in the phrase “the term of the lease arrangement is at least 1 year” is ambiguous. “Term” could mean either the duration of the arrangement as a matter of fact or the formal term provision of the arrangement as prescribed by contract. To clarify in the regulatory text that arrangements that last for at least 1 year as a matter of fact satisfy the requirement, we are further modifying §411.357(a)(2), (b)(3), and (d)(1)(iv). We are removing the word “term” and simply stating that the duration of the arrangement must be at least 1 year. Finally, we are taking this opportunity to clarify that our statement in the preamble regarding compliance with the 1-year term requirement represents CMS’ existing policy.

Comment: One commenter generally supported our proposal, but suggested that CMS rely on State law contract principles to determine compliance with the 1-year term requirement of the physician self-referral law.

Response: As stated elsewhere in this section, we do not believe that State law principles are appropriate for determining compliance with the physician self-referral law, including the 1-year requirement.

Upon review and consideration of the comments regarding the 1-year term requirement, we are finalizing revised regulatory language for the exceptions at §411.357(a)(2), (b)(3), and (d)(1)(iv). The revised language at §411.357(a)(2) provides that the duration 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 a new lease arrangement for the same space

during the first year of the original lease arrangement. We are finalizing similar language for §411.357(b)(3) and (d)(iv). The revised regulatory text clearly states our current policy that an arrangement need only last 1 year to satisfy the 1-year term requirement of the exceptions for the rental of office space, the rental of equipment, and personal service arrangements.

c. Holdover Arrangements

The exceptions at §411.357(a), (b), and (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 proposed to amend the holdover provisions at §411.357(a)(7), (b)(6), and (d)(1)(vii) to permit indefinite holdovers, provided that certain additional safeguards are met. In the alternative, we proposed 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 proposed 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), (b), and (d) developed over the course of our rulemaking in response to inquiries regarding the expiration, termination, and renewal of arrangements. See 80 FR 41916 through 41917 for a discussion of the development of the holdover provisions.

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 reconsidered our previous position and proposed 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 that take into account 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), (b)(3), or (d)(1)(iv) (or it must satisfy the requirements of the exception for fair market value compensation at §411.357(l), if applicable). 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 proposed to revise the holdover provisions at §411.357(a)(7), (b)(6), and (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 proposed 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 arrangement would be considered renewed for a new 2-year period). We stated in the proposed rule our belief 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 sought 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), (b)(6), and (d)(1)(vii), we proposed 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. Currently, the renewed arrangement must continue to satisfy all the requirements of the exception, including the requirement that the compensation is consistent with fair market value. We proposed 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. In addition, as is the case currently, 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 solicited 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.

We are finalizing the proposed indefinite holdover provisions for the exceptions at §411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase “made for less than 1 year” at §411.357(l)(2). The following is a summary of the comments we received.

Comment: The majority of commenters supported our proposal to permit indefinite holdovers of arrangements that continue on the same terms and conditions as an expired arrangement, provided all elements of the applicable exception continue to be satisfied during the holdover. No commenter suggested that additional safeguards would be necessary, and no commenter favored holdover provisions with potentially shorter durations, such as 1, 2, or 3 years. One commenter stated that additional safeguards for holdovers arrangements are not necessary, because, according to the commenter, an arrangement that continues after the expiration of a term in a contract, but is contemporaneously documented during the “holdover”

period, may satisfy the writing requirement of an exception even if there is no special regulatory provision relating to holdovers.

Response: We appreciate the commenters' support, and we are finalizing the proposed indefinite holdover provisions. We agree with the commenter that, even without a holdover provision, an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception, provided that the parties had sufficient contemporaneous documentation of the arrangement. Nevertheless, we believe that the proposed holdover provision will facilitate compliance without posing a risk of program or patient abuse. If a written contract with an explicit term provision expires on its own terms, but the parties nevertheless continue the arrangement past the expiration, the expired written contract by its own terms does not apply to the continued arrangement. For this reason, without a holdover provision, an expired written contract, on its own, could not satisfy the writing requirement of an applicable exception. Without additional supporting documentation, there may be gaps in compliance, as it may take some time after the expiration of the written contract to generate sufficient documents evidencing the course of conduct between the parties after the contract expired. In contrast, with a holdover provision, parties can rely in part on the expired written contract to satisfy the writing requirement for the holdover period. We note, however, that parties relying on the holdover provisions must still have contemporaneous documents establishing that the holdover continued on the same terms and conditions as the immediately preceding arrangement. That is, a party must be able to establish that it satisfied the requirements for the holdover provisions at §411.357(a)(7), (b)(6), or (d)(1)(vii) for referrals made during the holdover period.

Comment: One commenter objected to our statement in the proposed rule that, if rental amounts fall below fair market value during a holdover, the lease arrangement would no longer

satisfy the fair market value requirement of the exception at §411.357(a). According to the commenter, our statement implies that an arrangement that falls out of fair market value during its term loses protection under the exception. The commenter suggested that we retract the statement in the final rule. Another commenter supported our proposal to require holdover arrangements to continue to satisfy the applicable fair market value requirement during the holdover, but requested that CMS confirm that fair market value is determined at the commencement of the arrangement, taking into account the length of the term.

Response: The statement cited by the commenter regarding rental amounts falling below fair market value referred only to the application of the relevant fair market value requirement during a holdover. We believe that ongoing compliance with the fair market value requirement during the holdover is necessary to prevent program or patient abuse. Regarding the fair market value requirement during the original term, we expect parties to make a determination of fair market value at the time the financial relationship is created. (See 73 FR 48739.) The exception at §411.357(a)(4) requires rental charges to be consistent with fair market value “over the term of the arrangement,” but we note that fair market value is expressed as a range of values. We caution that rental payments may cease to be consistent with fair market value in long-term arrangements.

Comment: One commenter stated that it may be difficult for an arrangement to satisfy the fair market value requirement during a holdover that lasts for more than 1 year. The commenter requested guidance on how the fair market value requirement should be analyzed in a multiple year holdover.

Response: As noted elsewhere in this section, the requirement that an arrangement continue to meet the fair market value requirement throughout the holdover is necessary to prevent program or patient abuse. Parties relying on a holdover provision bear the risk of

fluctuations in the relevant market that may cause an arrangement to no longer satisfy the applicable fair market value requirement. In most instances, fair market value is expressed as a range, and minor fluctuations in market value may not cause an arrangement to become noncompliant. (See 73 FR 48739.) However, as soon as a holdover arrangement ceases to meet all the requirements of an applicable exception, including the fair market value requirement, referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permissible. It is up to the parties to determine the best way to analyze fair market value during a holdover. The best means of ensuring ongoing compliance is to enter into a new agreement in a timely manner after a previous contract expires, and to reassess fair market value to the extent that is necessary at the time of the renewal.

Comment: One commenter requested that CMS permit changes to the terms and conditions of an arrangement during a holdover, provided that the changes do not impact compliance with the elements of an applicable exception.

Response: Under the revised regulations, an indefinite holdover lease arrangement or personal service arrangement is permitted if the arrangement continues on the same terms and conditions as the immediately preceding arrangement. As stated in the proposed rule, the holdover arrangement must continue on the same terms and conditions because frequent renegotiation of short term arrangements poses a risk of program or patient abuse. (See 80 FR 41917). If parties were permitted to amend the terms and conditions of an arrangement in the course of the holdover, then parties would be able to frequently renegotiate the terms of the arrangement during the holdover in a manner that could take into account the volume or value of referrals. Thus, parties are not permitted to amend the terms and conditions of an arrangement during a holdover, because such changes pose a risk of program or patient abuse.

Comment: One commenter stated that many leases provide that the rental amount will increase if the tenant holds over after the lease expires on its own terms. The commenter requested guidance on how the fair market value requirement would apply to increased rental amounts during the holdover period.

Response: In Phase III, we stated that lessors can charge a holdover premium, “provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties.” (See 72 FR 51045). The same principles apply to the indefinite holdover provisions that we are finalizing. The rental amount with the holdover premium must satisfy the fair market value requirement when the original agreement expires and throughout the holdover.

We caution that, depending on the facts and circumstances, the failure to apply a holdover premium that is legally required by the original arrangement may constitute a change in the terms and conditions of the original arrangement. In such circumstances, the “holdover” arrangement will not meet the requirement at §411.357(a)(7)(ii) that the arrangement continue on the same terms and conditions as the immediately preceding arrangement. In addition, the failure to charge a holdover premium may constitute the forgiveness of a debt, thus creating a secondary financial relationship between the parties that must satisfy the requirement of an applicable exception.

Comment: One commenter supported the proposal to allow parties to renew arrangements of any duration, including arrangements of 1 year or more, under the exception for fair market value compensation at §411.357(l). Several other commenters requested that an indefinite holdover provision, similar to the proposal for lease arrangements and personal service

arrangements, be applied to the exception for fair market value compensation. The commenters stated that the exception for fair market value compensation is similar in many respects to the exceptions for lease arrangements and personal service arrangements, and therefore, the commenters saw no reason to include an indefinite holdover provision in the latter exceptions while not including such a provision in the exception for fair market value compensation.

Response: We believe that permitting parties to renew arrangements of any length under the exception for fair market value compensation, provided that the terms of the arrangement and the compensation for the same items or services do not change, affords parties sufficient flexibility without posing a risk of program or patient abuse. For this reason, we do not believe that a separate holdover provision is necessary for the exception for fair market value compensation. We note that nothing in the exception requires parties to renew the arrangement in writing. However, the parties must have written documentation establishing that the renewed arrangement was on the same terms and conditions as the original arrangement.

Comment: One commenter stated that the exception at §411.357(l) as it is currently worded does not prohibit the renewal of arrangements with a term of more than 1 year. The commenter stated that our proposed revision was unnecessary and requested clarification in the final rule that the exception has always permitted the renewal of arrangements of more than 1 year.

Response: The exception as it is currently written permits arrangement for less than 1 year to be renewed any number of times if the terms of the arrangement and compensation for the same items or services do not change. There is no requirement that the arrangement of less than 1 year be renewed in writing. The arrangement can be renewed by course of conduct, and the writing requirement for the renewal period would be satisfied (assuming that it was satisfied for the initial term) if the parties had documents establishing that the arrangement continued on

the same terms and conditions. Under our proposed rule, arrangements for 1 year or longer could also be renewed by course of conduct, provided that the parties have documentation establishing that the terms of the arrangement and the compensation for the same items or services do not change during the renewal.

It is true that the exception as currently written does not expressly prohibit parties from renewing arrangements of 1 year or longer. Nonetheless, given the purpose of the exception when it was first established, we believe the better reading of the exception does not rely on reading missing words into the text and, therefore, we are not retracting our statement from the proposed rule.

Comment: One commenter stated that the exception for fair market value compensation currently requires that the term of the arrangement must be specified in writing. The commenter requested that CMS create a “safe harbor” timeframe of 6 months for arrangements that do not specify the timeframe in writing.

Response: We decline to create a “safe harbor” timeframe for the exception for fair market value compensation. We note, however, that the timeframe can be specified in a collection of documents setting out the arrangement in writing.

After reviewing the comments, we are finalizing the proposed indefinite holdover provisions for the exceptions at §411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase “made for less than 1 year” at §411.357(l)(2). We believe that lease arrangements and personal service arrangements that continue on the same terms and conditions and satisfy the requirements for the new holdover provisions (including ongoing compliance with all the requirements of an applicable exception) do not pose a risk of program and patient abuse. We also believe that allowing renewals of an arrangement of any timeframe under the exception for fair market value compensation at §411.357(l), provided the

arrangement is renewed on the same terms and conditions, affords DHS entities additional flexibility in their arrangements and facilitates compliance, without posing a risk of program or patient abuse; we remind stakeholders that the renewed arrangement must satisfy all the requirements of the exception at the time a referral for DHS is made.

The indefinite holdover provisions will be available to parties on the effective date of this final rule. Parties who are in a valid holdover arrangement under the current 6-month holdover provisions on the effective date of this final rule may make use of the indefinite holdover provisions that we are finalizing, provided that all the requirements of the new holdover provisions are met. On the other hand, if an arrangement does not qualify for the 6-month holdover under the current regulations at §411.357(a)(7), (b)(6), or (d)(1)(vii) on the effective date of this rule (for example, if the holdover has lasted for more than 6 months as of the effective date of the rule), then the parties cannot make use of the indefinite holdover provisions.

4. Definitions

In the proposed rule, we proposed to revise several definitions in our regulations to improve clarity and ensure proper application of our policies. We describe below the specific proposals. We are now finalizing the revised definitions as proposed, without additional modification.

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. As explained at 80 FR 41918, we proposed to revise the definition of “remuneration” at §411.351 to make it clear that the provision of an item, device, or supply that is used for one or more of the six purposes listed in the statute, and no other purpose, does not constitute remuneration.

We received two comments in support of our proposed revision of the definition of “remuneration.” We are finalizing the revisions to §411.351 as proposed.

Although we did not propose regulatory revisions, we noted in the proposed rule that we are concerned about potential confusion 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 several written inquiries 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 the purposes of the physician self-referral law. We are taking the opportunity afforded by this rulemaking to address this issue.

In a “split bill” arrangement, a physician makes use of a DHS entity’s resources (for example, examination rooms, nursing personnel, and supplies) to treat the DHS entity’s patients. The DHS entity 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 the 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.

The following is a summary of the comments we received.

Comment: The overwhelming majority of those that commented on the issue of split billing and remuneration agreed that a physician's use of hospital resources when treating hospital patients does not constitute remuneration between the parties for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the resources and services it provides and the physician bills the payor for his or her services. One commenter asked CMS to confirm that our statement is a clarification of existing law. Several other commenters requested that we codify our position in regulatory text. Two commenters requested that we confirm our interpretation by amending the definition of "remuneration" at §411.351.

Response: Our discussions in the preamble to the proposed rule and in this final rule regarding remuneration and split bill arrangements is a statement of CMS' existing policy. We did not propose any regulatory revisions in the proposed rule because we did not think it necessary, and therefore, we cannot make revisions to the regulatory text at this time.

Comment: One commenter asked whether a hospital's promise to grant a physician organization exclusive use of the hospital's space constituted remuneration for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the space it provides and the physician bills the payor for his or her services. According to the commenter, in Kosenske the hospital promised a physician group exclusive use of the hospital's space.

Response: Our clarification regarding split bill arrangements and remuneration applied only to the use of a hospital's space, items, and equipment. We are not addressing exclusive use of space in this final rule with comment period.

Following our review of the comments, we are confirming our existing policy that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients does not constitute remuneration under the physician self-referral law, 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 emphasize that this statement reflects our interpretation of the term "remuneration" and policy on the issue.

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 the 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 the 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 the 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 the 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 proposed 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 the 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 (c)(2)(iv)(B). Guidance regarding physicians who stand in the shoes of their physician organizations may be found on our website at <http://www.cms.gov/Medicare/Fraud-and->

[Abuse/PhysicianSelfReferral/FAQs.html](#). Specifically, consistent with our response in Frequently Asked Question #12318, for the 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, we proposed to 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.

The following is a summary of the comments we received.

Comment: One commenter disliked the proposed revisions to the “stand in the shoes” regulations at §411.354(c)(3)(i), stating that, prior to the revision, a physician who did not stand in the shoes of his or her physician organization was not a “party” to any compensation arrangement between the physician organization and a DHS entity. The commenter recognized

that such a physician's referrals had to be considered when determining the compliance of the compensation arrangement with the volume or value standard in various exceptions, but did not agree that the identifier "party" should be applied to a physician who does not stand in the shoes of his or her physician organization. Another commenter was concerned that this revision would create direct compensation arrangements between a DHS entity and the physician employees of a physician organization who do not stand in the shoes of the physician organization under the current regulations.

Response: We disagree that the revised regulation at §411.354(c)(3)(i) will have the effect of transforming physicians who do not stand in the shoes of their physician organizations into "parties" to a compensation arrangement between a DHS entity and the physician organization. In many exceptions, the volume or value standard (described in detail elsewhere in this section) is expressed by prohibiting compensation that is determined in a manner that takes into account the volume or value of referrals or other business generated "between the parties." Most exceptions also include a requirement that the writing evidencing the arrangement be signed by the "parties." In interpreting the physician self-referral exceptions, we attach the same meaning to a term or phrase wherever it is used, unless otherwise specified explicitly in the regulation text. To do otherwise would introduce confusion into the regulations, as a single term or phrase could have different meanings in different exceptions, or even in the same exception if the term or phrase is used more than once. Therefore, if a physician is considered a "party" for the purposes of the volume or value standard, he or she would be considered a "party" for the purposes of the signature requirement.

As the commenter correctly recognized, the referrals of all physicians in a physician organization—regardless of whether the physicians stand in the shoes of the physician organization—must be considered when determining compliance with the volume or value

standard in the exceptions at §411.355 and §411.357. Thus, the physicians who do not stand in the shoes of the physician organization would nonetheless be considered “parties” for the purposes of analyzing compliance with the volume or value standard. Given our uniform interpretation of terms and phrases used in the physician self-referral regulations, under our current regulations, even physicians who do not stand in the shoes of their physician organizations may be required to meet the signature requirements for “parties.” We do not believe there is a need to include these physicians as “parties” that must sign the writing evidencing the arrangement between a DHS entity and a physician organization. The revision to §411.354(c)(3)(i) is merely intended to alleviate the burden on physician organizations related to the signature requirements in many of the exceptions at §411.355 and §411.357 that would otherwise require the signatures of physicians who do not stand in the shoes of their physician organizations. It does not affect the regulations at §411.354(c)(1)(ii) or (c)(2)(iv), which identify physicians who are deemed to stand in the shoes of their physician organizations and have the same compensation arrangements as their physician organizations. Moreover, we note that our determination of which physicians are “parties” for the purposes of applying the exceptions at §411.355 and §411.357 should not affect which physicians and entities are considered parties to a contract under State or any other law.

Comment: One commenter requested additional clarification regarding our statements in the proposed rule regarding the “stand in the shoes” provisions at §411.354(c)(3)(i). Specifically, the commenter was concerned that the language in the proposed rule could be construed as conflating what it understands to be two separate analyses: (1) the analysis of a direct compensation arrangement between a DHS entity (and the resulting “deemed” direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization); and (2) the potential existence of an indirect compensation

arrangement between the DHS entity and non-owner physicians of the physician organization (employees, independent contractors, and titular owners). As to the second analysis, the commenter recognized that the question of whether aggregate compensation to a non-owner physician (that is, one who does not stand in the shoes of the physician organization) varies with or takes into account the volume or value of referrals or other business generated for the DHS entity must be considered for the purposes of identifying any indirect compensation arrangements, but questioned why “downstream compensation” to non-owner physicians would factor into analyzing the direct compensation arrangement between the DHS entity and the physician organization (and the “deemed” direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization).

Response: Current §411.354(c)(3)(i) states 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. Further, when applying the exceptions at §411.355 and §411.357 to arrangements where a physician stands in the shoes of his or her physician organization, §411.354(c)(3)(i) states that the relevant referrals and other business generated “between the parties” are referrals and other business generated between the DHS entity and the physician organization, including all members, employees, and independent contractor physicians. In the first analysis noted by the commenter, the parties must consider whether the compensation under the arrangement between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated by any physician in the physician organization, regardless of whether the physician stands in the shoes of the physician organization. Because a physician who stands in the shoes of his or her physician organization has the same compensation arrangements as the physician organization, the result of this analysis would be the same for any “deemed” direct compensation arrangement

between the DHS entity and a physician who stands in the shoes of the physician organization. Where no direct or “deemed” direct compensation arrangement exists between a physician and a DHS entity, parties should consider whether an indirect compensation arrangement exists under §411.354(c)(2). Nothing in revised §411.354(c)(3)(i) impacts the analysis regarding whether an indirect compensation arrangement exists between a physician and a DHS entity.

We are uncertain what “downstream compensation” the commenter believes is factored into the analysis of the direct compensation between a DHS entity and the physician organization with which it has a compensation arrangement. As noted earlier, compensation between a DHS entity and a physician organization may not be determined in a manner that takes into account the volume or value of referrals and other business generated by any physician in the physician organization, including physicians who do not stand in the shoes of the physician organization. The compensation from the physician organization to its employed or contracted physicians is relevant to whether an indirect compensation arrangement exists between the DHS entity and a physician.

Comment: One commenter opposed the proposed revisions to the “stand in the shoes” rules at §411.354(c)(3)(i), stating that the effect of considering all referrals from a physician organization when determining whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals between the parties would be to convert presently lawful transactions into a violation of the physician self-referral law.

Response: The “stand in the shoes” regulations, including §411.357(c)(3)(i) specifically, were established in Phase III and became effective on December 4, 2007 (72 FR 51028). Our Phase III policy considered all physicians in a physician organization to stand in the shoes of the physician organization, and §411.354(c)(3)(i) originally stated that for the purposes of 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 the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians). Both the policy and §411.354(c)(3)(i) were amended in the FY 2009 IPPS final rule and became effective on October 1, 2008. The regulation currently states that when applying the exceptions in §411.355 and §411.357 of this part 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). Thus, at all times, the regulation at §411.354(c)(3)(i) has required parties to consider the referrals of all physicians in a physician organization—regardless of whether they stand in the shoes of the physician organization—when analyzing whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals or other business generated “between the parties.” We do not believe that, under any iteration of §411.354(c)(3)(i) or the regulation finalized in this final rule, an arrangement between a DHS entity and a physician organization could comply with the volume or value standard in an applicable exception if the compensation under the arrangement is determined in a manner that takes into account the volume or value of referrals or other business generated by the physicians who do not stand in the shoes of the physician organization.

As a result of the comments, we are finalizing our proposed revisions to the “stand in the shoes” regulations at §411.354(c)(3)(i).

c. Locum Tenens Physician (§411.351)

The term “locum tenens physician” was first defined for the purposes of the physician self-referral law in Phase I (66 FR 954). The definition of “locum tenens physician” adopted in

Phase I used the phrase “stand in the shoes.” (See 80 FR 41919 through 41920.) 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” provisions are specific to compensation arrangements and described in our regulations at §411.354(c).

We proposed 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 at §411.354(c) are specific to compensation arrangements and are separate and distinct from the definition of a locum tenens physician. However, to eliminate unnecessary verbiage and to avoid any potential ambiguity, we proposed to revise the definition of locum tenens physician at §411.351 by removing the phrase “stands in the shoes.”

We received no comments opposing our proposal to revise the definition of locum tenens at §411.351 by removing the phrase “stands in the shoes,” and we are finalizing the revisions to §411.351 as proposed.

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. The exception applies to several categories of securities, including securities that are traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD). This exception is codified in our regulations at §411.356(a), which closely mirrors section 1877(c) of the Act.

Through a question posed to us by a stakeholder, 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 researched 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. (See 80 FR 41920 for a summary of our research).

We proposed 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 did not propose 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 solicited comments 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.

We received no comments on our proposal to update the provision at §411.356(a)(1) to except ownership or investment interest in securities listed for trading on an electronic stock market or over-the-counter quotation system, provided that quotations are published on a daily basis and trades are standardized and publicly transparent. We are finalizing the revisions to §411.356(a) as proposed.

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 areas, 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 (l), the exceptions for payments by a physician and fair market value compensation, respectively. We note that the commenter specifically described lease arrangements where the lessee had exclusive, but only periodic, use of the premises, equipment, and personnel. In response, we declined to permit office space lease arrangements 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 office 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 another person or entity'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 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 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.

In general, a license—or permission—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, giving the lessee an exclusive “right against the world” (including a right against the lessor) with respect to the leased property, but a license is a mere privilege to act on another’s property and does not confer a possessory interest in the property. A license may be granted in writing or orally, and ordinarily does not convey an exclusive right. For a license to convey the right to exclusive use, it must be specified in the writing that documents the license. As with a license, a “timeshare” arrangement, as we use the term in this final rule, does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of their owner, but rather confers a privilege to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the arrangement.

c. New Exception

Under our current regulations, an arrangement that includes the use of office space, as timeshare arrangements commonly do, must be analyzed under the exception for the rental of office space. The exceptions for payments by a physician and fair market value compensation arrangements 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 permit the use of office space, equipment, personnel, items, supplies, or services 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 health care services (especially in rural and underserved

areas), we proposed a new exception at §411.357(y) that would have applied to 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 E/M 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 E/M services, (ii) is used only to furnish DHS that is incidental to the physician's E/M services and furnished at the time of such E/M 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 have applied 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 solicited comments 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 also solicited comments on whether the exception should be limited to arrangements in rural and underserved areas.

We proposed to protect only those timeshare arrangements under which the physician uses the licensed premises, equipment, personnel, items, supplies, and services predominantly for the E/M 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 solicited comments 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 proposed 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 E/M visit and furnished contemporaneously with that visit. We noted that such a requirement would not affect the manner in which the DHS is billed (for example, “incident to” a physician’s service or directly by an NPP). Because we believe that DHS that is “incidental to” the patient’s E/M 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, we proposed 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 proposed to require that the equipment be located on the licensed premises; that is, in the office suite. We solicited comments on these requirements and limitations. Specifically we solicited 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 proposed to prohibit certain per unit-of-service and percentage compensation methodologies for determining the license fees under timeshare arrangements. Under the exception as proposed, parties could 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 solicited 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 solicited comments on the proposed new exception for timeshare arrangements and any additional criteria that may be necessary to safeguard against program or patient abuse.

We are finalizing an exception at §411.357(y) for timeshare arrangements with several modifications to our proposal. Importantly, the exception as finalized is not available for arrangements that transfer control—that is, a “right against the world”—over the premises that are the subject of the arrangement. Rather, the exception protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services

of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. However, because the public comments addressed the proposal to establish an exception for remuneration provided by a licensee to a licensor under an arrangement for the use of the licensor's premises, equipment, personnel, items, services, or supplies, the comment summaries below reflect the use of "licensor" and "licensee" terminology. This does not affect final §411.357(y), which is an exception for "remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services," and does not use the terms "license," "licensee," or "licensor." In our responses to the public comments, we refer to the party granting a right or permission to use its premises, equipment, personnel, items, supplies, or services variously as the "grantor" or "party granting permission."

The following is a summary of the comments we received.

Comment: Citing a variety of reasons, the majority of commenters supported the establishment of an exception for timeshare arrangements. Many commenters stated that the exception for timeshare arrangements will promote important policy goals. One commenter commended CMS for recognizing the need for arrangements that support specialists who would like to provide services in rural areas that cannot maintain a full-time specialist. Another commenter expressed a belief that the exception will help to provide E/M services that may be needed on only a periodic basis to assist a physician in diagnosing or treating his or her patients. A third commenter stated that the exception will facilitate patient convenience and coordination and continuity of care. Two commenters that supported the establishment of the exception described how current arrangements for the limited use of space and equipment must be structured to fit within some combination of the existing exceptions for the rental of office space, rental of equipment, personal service arrangements, and fair market value compensation, which

creates scheduling and other operational difficulties. One of these commenters identified certain requirements of these exceptions that reduce flexibility and potentially inhibit patient access, such as the “exclusive use” requirement in the exceptions for the rental of office space and the rental of equipment. In the commenters’ view, the new exception for timeshare arrangement offers the promise of simplicity and will allow for much greater functionality and creativity in arrangements for patient services. However, one of these commenters proclaimed the proposed exception too narrow.

Response: After careful consideration of the comments we received in response to the proposed exception, and for the reasons discussed in the proposed rule (80 FR 41921-22), we continue to believe that timeshare arrangements may serve to ensure adequate access to needed health care services. We are finalizing the exception for timeshare arrangements at §411.357(y) with the following modifications: (1) regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and: (i) a hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment included under the timeshare arrangement may be in the same building (as defined at §411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. We believe that the other safeguards in the exception finalized here are necessary at

this time to protect against program or patient abuse. In order not to inhibit flexibility for parties to arrangements involving office space, equipment, personnel, items, supplies or services, the existing exceptions to the physician self-referral law remain available to parties that wish to structure their arrangements in a way that satisfies all of the requirements of the applicable exception(s).

Comment: One commenter stated that its clients “successfully and without any type of abuse long utilized ‘Time Share Agreements’ with a physician organization either as the landlord (licensor) or as a tenant (licensee)” prior to the publication of Phase III. The commenter described a timeshare arrangement as one under which a physician is “embedded” in another party’s medical practice with permission to use the space, equipment and personnel of the practice for a fair market payment. The commenter depicted the Phase III commentary as prohibiting such arrangements unless they can be arranged so that the embedded physician has the exclusive use of patient care areas and equipment of the practice into which the physician is embedded. Based on its reading of the Phase III commentary, the commenter welcomed the proposed exception for timeshare arrangements, declaring that the new exception is warranted because the types of arrangements it would cover are different from the lease arrangements described at §411.357(a) and (b).

Response: The Phase III remarks referenced by this commenter related to an arrangement described to CMS in response to the Phase II rulemaking as including the exclusive—but only periodic—use of office space, personnel, waiting areas, furnishings, and equipment. Based on our prior guidance, we declined to permit office space leases to be eligible for the exceptions for fair market value compensation at §411.357(l) and payments by a physician at §411.357(i) (72 FR 51044 through 51045). Our position regarding the availability of the exceptions for fair market value compensation at §411.357(l) and payments by a physician

at §411.357(i) for arrangements involving the rental of offices space has not changed.

As we described in the proposed rule, we believe that timeshare arrangements may improve access to needed care, especially in rural and underserved areas, by facilitating part-time or periodic access to physicians in communities where the need for the physician is not great enough to support the full-time services of the physician or where physicians, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement (80 FR 41921). The new exception at §411.357(y) is intended to promote access to needed services and provide parties with an option for structuring arrangements in the way that best suits the needs of the parties and the community in which the timeshare arrangement is located.

We note that we do not agree with the commenter's description of a timeshare arrangement as one in which a physician is embedded in another party's medical practice with permission to use the space, equipment, and personnel of the practice for a fair market payment. Although such an arrangement may qualify as a timeshare arrangement under the new exception depending on the facts and circumstances, we do not intend to limit the types of arrangements that may qualify as timeshare arrangements to those in which a physician is located within another physician's practice.

Comment: A commenter expressed concern that the use of the terms "licensor" and "licensee" could prohibit use of the exception for otherwise qualifying arrangements that, through a quirk of State law or the arrangement, are something other than a "license" under State law. Another commenter feared that compliance with the physician self-referral law could turn on considerations such as how an arrangement might be classified under landlord/tenant law or technical "lease" versus "license" considerations.

Response: Nothing in §411.357(y) is meant to impact parties' rights and obligations as

construed under State law. The exception is intended to address the challenge of satisfying the requirements of an available exception to the physician self-referral law in the case of arrangements that merely permit the use of office space without conveying a possessory leasehold interest in the premises or a “right against the world” with respect to the office space that is the subject of the arrangement.

We used the term “license” in the proposed exception at §411.357(y) to describe the type of arrangement that could qualify for the exception. Generally, a license grants permission to do something which, without the license, would not be allowable. See *Barnett v. Lincoln*, 162 Wash. 613, 299 P. 392, 394. It is merely a personal privilege or permissive use of the licensor’s premises, equipment, personnel, items, supplies, or services. We contrast this with a “tenancy” or “possessory leasehold interest” which implies some interest in the office space leased. See *Klein v. City of Portland*, 106 Or. 686, 213 P. 147, 150; *Vicker v. Byrne*, 155 Wis. 281, 143 N.W. 186, 188. One fundamental way that a license differs from a lease is that ownership and control of the property remains with the licensor.

Upon further reflection and after careful consideration of the issues raised by the commenters, we agree that the use of the term “license” without a definition that is specific to the exception at §411.357(y) could introduce unnecessary confusion into the regulations and potentially exclude non-abusive arrangements that we believe should qualify for the exception. The terminology used by the parties in the documentation that describes and supports the timeshare arrangement should not control whether the parties can satisfy the requirements of the exception. Whether the arrangement is styled as a “license” or otherwise is not dispositive when determining compliance with new §411.357(y). Rather, the facts and circumstances of the arrangement are critical to its compliance with the requirements of the exception. Therefore, we are not finalizing §411.357(y) to include the terms “license,” “licensor,” or “licensee.” As

finalized, §411.357(y) includes a set of requirements for arrangements that we consider to be “timeshare” arrangements that do not violate the physician self-referral law’s referral and billing prohibitions.

Parties wishing to avail themselves of the exception at §411.357(y) need not utilize any particular terminology, provided that the arrangement itself grants one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party to the arrangement. Moreover, the arrangement may qualify for protection under the final exception even if the grant of permission to use the premises, equipment, personnel, items, supplies, or services provides for exclusive use of the premises, equipment, personnel, items, supplies, or services or has a duration of 1 year or more. However, the timeshare arrangement may not convey a possessory leasehold interest in the office space that is the subject of the arrangement. Where control over office space is conferred on a party such as to give that party a “right against the world” (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at §411.357(a) in order not to run afoul of the physician self-referral law.

Again, what is imperative for compliance with the physician self-referral law when relying on the exception at §411.357(y) is that the timeshare arrangement grant to one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party without conveying a possessory leasehold interest in the office space that is the subject of the arrangement. Of course, the arrangement must also satisfy the other requirements of the exception for timeshare arrangements as finalized at §411.357(y) in this final rule. And, regardless of the structure of the arrangement or the terminology used by the parties, we do not intend to protect potentially abusive arrangements such as exclusive-use timeshare arrangements that essentially function as full-time leases for medical practice sites; arrangements in which

physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician's referrals.

Comment: One commenter requested clarification that a medical foundation model physician practice would be a permitted licensee under a timeshare arrangement protected by the new exception.

Response: A medical foundation model physician practice may utilize the new exception at §411.357(y). Because we are not dictating the roles of the parties to a timeshare arrangement, a medical foundation model physician practice may qualify as the party granting permission to use its premises, equipment, personnel, items, supplies, or services, or as the party to whom the permission is granted.

Comment: Many commenters, although supportive of an exception to protect timeshare arrangements, urged CMS not to limit the application of the exception for timeshare arrangements to rural or underserved areas. One of the commenters noted that non-rural areas and areas not determined to be underserved may nonetheless experience a practical shortage in certain specialties. Two of the commenters indicated that the exception for timeshare arrangements will address a longstanding problem that not all physicians are interested in committing to rent or accepting ownership or control over the premises, equipment, personnel, and supplies of a DHS entity. One of these commenters also stated that, although the exception would add much needed flexibility, especially for areas where there are shortages of physicians (and, in particular, specialists), patients in all areas would benefit from these arrangements. This commenter stated its belief that the risk of program abuse would be minimal given the proposed safeguards, which should adequately address any fraud and abuse concerns.

Response: We agree with the commenters. We did not propose to limit the exception to timeshare arrangements in rural or underserved areas, and are not including such a limitation in the exception at §411.357(y) finalized here.

Comment: A commenter took issue with our statement in the preamble to the proposed rule indicating that timeshare arrangements structured as licenses “cannot satisfy the requirements of [the exception for the rental of office space] because a license generally does not provide for exclusive use of the premises.” The commenter expressed concern that this statement could call into question many existing arrangements that are styled as licenses yet satisfy the requirements of the exception at §411.357(a), including the “exclusive use” requirement. Another commenter recommended that CMS not finalize the proposed exception for timeshare arrangements, stating that it is not necessary because timeshare leases or “licenses” fit within the existing exceptions. Both of the commenters were concerned that the establishment of a new exception could cast doubt whether longstanding arrangements have been in compliance with the physician self-referral law. These commenters and a third commenter recommended that we clarify that license arrangements may satisfy the requirements of the exception for the rental of office space, depending on the facts and circumstances of the arrangement.

Response: The establishment of the new exception for timeshare arrangements at §411.357(y) is not intended to call into question the compliance of any prior or existing arrangement or type of arrangement involving the use of office space, equipment, personnel, items, supplies, or services. Our questioning in the proposed rule of whether an arrangement (as it relates to office space) can satisfy the requirements of the exception at §411.357(a) pertained only to those arrangements that involve the use of office space on a non-exclusive basis or for a term of less than 1 year. Although we stated our belief that a license generally does not provide

for exclusive use of the premises (80 FR 41921), we did not rule out the possibility that it may.

A financial relationship between a physician (or immediate family member of the physician) and a DHS entity must satisfy the requirements of an applicable exception to the physician self-referral law to avoid the law's billing and referral prohibitions. Where more than one exception is available to protect a financial relationship, we do not dictate which exception the parties must use. The exception for timeshare arrangements finalized at §411.357(y) establishes another—not a replacement—exception for parties to a timeshare arrangement. If a timeshare arrangement includes the exclusive use of office space but does not convey a possessory leasehold interest in the office space that is the subject of the arrangement, the new exception at §411.357(y) is available to protect the arrangement (provided that all other requirements of the exception are satisfied). Depending on the facts and circumstances of the arrangement, it may also qualify for the exception at §411.357(a). In short, the parties to a timeshare arrangement may elect to use any available exception(s) to protect the arrangement. However, where control over office space is conferred on a party such as to give that party a “right against the world” (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at §411.357(a) in order not to run afoul of the physician self-referral law.

Comment: A commenter requested that we eliminate the proposed restriction on the hospital (or other DHS entity) being the licensee in a timeshare arrangement. The commenter described a scenario where the purpose of the timeshare arrangement is to embed a hospital-employed physician in an independent physician practice, which the commenter maintained is a convenient practice setting for Medicare beneficiaries. The commenter requested that we modify the exception at §411.357(y) to accommodate timeshare arrangements in which the physician (or a physician organization) is the licensor and the DHS entity is the licensee. A few commenters

believed that the proposed requirement that the licensor be a hospital or a physician organization is overly limiting. Two of these commenters noted that hospitals often employ physicians and may require timeshare arrangements that include space in a physician or physician organization's clinic. These commenters requested that we permit hospitals or other entities that employ physicians to be the licensee and still qualify for the protection of the exception. One of the commenters also requested that we permit physician organizations, rather than physicians, to be the licensee under a protected timeshare arrangement. This commenter stated that it is more common for a physician organization or professional corporation to enter into a timeshare arrangement than an individual physician in his or her personal capacity. Another of the commenters noted that many hospitals have affiliates (such as real estate subsidiaries and management service organizations) that act as the licensor in timeshare arrangements. The commenter recommended that hospital affiliates be included as permissible licensors under the exception.

Response: After consideration of the commenters' suggestions, we believe that it would not pose a risk of program or patient abuse to permit timeshare arrangements under which the hospital or physician organization is the party using the premises, equipment, personnel, items, supplies, or services of a physician (or the physician organization in whose shoes the physician stands under §411.354(c)), provided that the arrangement satisfies all other requirements of the exception. We do not believe, nor did any commenters suggest, that it is necessary to permit other types of DHS entities, such as independent diagnostic testing facilities or laboratories, to be parties to timeshare arrangements to address the potential barriers to access to care described in the proposed rule. As we stated in the proposed rule, we believe that timeshare arrangements offered by independent diagnostic testing facilities or laboratories may serve to lock in referral streams from a physician licensee as a result of the physician's proximity to the DHS furnished

by such entities (80 FR 41922). The exception finalized at §411.357(y) only covers timeshare arrangements under which the DHS entity that is a party to the arrangement is a hospital or physician organization.

As to the request that we permit a physician organization, rather than a physician in his or her personal capacity, to enter into a timeshare arrangement, we refer readers to the discussion in the proposed rule regarding the analysis of arrangements between DHS entities and physician organizations where physicians may stand in the shoes of the physician organizations (80 FR 41911). There, we explained that, 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 exception at §411.357(y) would be available to protect a direct compensation arrangement between a physician and a hospital or physician organization of which the physician is not an owner, employee, or contractor, as well as “deemed” direct compensation arrangements between a physician standing in the shoes of his or physician organization and a hospital or physician organization of which the physician is not an owner, employee, or contractor. 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 to determine whether an indirect compensation arrangement exists. To protect an indirect compensation arrangement that exists as a result of remuneration provided by the entity furnishing DHS, the arrangement must satisfy the requirements of the exception at §411.357(p) for indirect compensation arrangements.

Timeshare arrangements between physicians and organizations, such as real estate subsidiaries and management service organizations, that are not themselves DHS entities should be analyzed under the rules regarding indirect compensation arrangements at §411.354(c). To protect an indirect compensation arrangement that exists as a result of a chain of financial relationships that runs hospital or physician organization--affiliate--physician, the arrangement must satisfy the requirements of the exception at §411.357(p) for indirect compensation arrangements.

Comment: One commenter urged CMS to finalize a bright-line standard that includes a precise percentage for the minimum amount of E/M services furnished under a timeshare arrangement. The commenter noted that, depending on the volume and types of services furnished, “predominant” could be more or less than 50 percent. Another commenter recommended that we define “predominant use” to require that more than 50 percent of patients receive E/M services in the timeshare office space.

Response: We decline to adopt either commenter’s suggestion. We attribute the common meaning to the term “predominant” and an attempt to define this standard further could inadvertently narrow the exception or constrain parties to a timeshare arrangement. We are not prescribing how parties determine compliance with §411.357(y)(3). Parties may determine predominant use through any reasonable, objective, and verifiable means, which, depending on the circumstances, may include assessing the volume of patients seen, the number of patient encounters, the types of CPT codes billed, or the amount of time spent using the timeshare premises, equipment, personnel, items, supplies, and services. Further, we note that this standard is used in the exception at §411.357(w) for nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) that are necessary and used predominantly to create, maintain, transmit, or receive electronic health

records, and we are not aware of any difficulty on the part of physicians and entities involved in such arrangements. We remind readers that the use of office space by the physician *solely* or *primarily* to furnish DHS to patients would not be protected by the new exception at §411.357(y).

Comment: One commenter objected to limiting the DHS furnished on the equipment covered by the timeshare arrangement to DHS that is incidental to the E/M services furnished by the physician at the time of the patient's visit. This commenter gave the example of a cardiologist ordering a test during a patient visit that is to be performed the following week when the ordering cardiologist is elsewhere and another cardiologist from the same physician practice is on the timeshare premises to supervise the test and read the results.

Response: We do not disagree with the commenter that there may be circumstances where a patient would benefit from receiving DHS but does not need an E/M service at the time of the furnishing of the DHS. However, a timeshare arrangement shifts to the party granted the use of the premises, equipment, personnel, items, supplies, or services only minimal financial risk related to the resources used to furnish DHS, and we cannot be certain that a timeshare arrangement would pose no risk of program or patient abuse without a limitation on the amount or scope of the DHS furnished using the timeshare equipment or in the timeshare premises. As we discussed in the proposed rule, our purpose in establishing the exception at §411.357(y) is to improve access to care and outcomes for our beneficiaries. It is not to facilitate the ability of physicians to furnish a full array of DHS in supplemental medical practice sites. Therefore, we are retaining in the final exception a requirement that the timeshare equipment is not used to furnish DHS other than DHS that are incidental to the patient's E/M visit and furnished contemporaneously with that visit. In light of our determination to permit hospitals and physician organizations to either grant or receive permission to use premises, equipment,

personnel, items, supplies, or services under the exception, we are modifying the regulation text slightly to clarify that the DHS furnished using equipment covered by the arrangement must be both: (1) incidental to the E/M service furnished by the physician using the equipment; and (2) furnished at the time of the E/M service to which it is incidental. We note that the requirement that the DHS be “incidental” to E/M services is unrelated to and does not affect the “incident to” billing rules elsewhere in our regulations (80 FR 41922).

Comment: Two commenters opposed the exclusion of certain DHS, such as advanced imaging, radiation therapy, and laboratory equipment, from the scope of the exception. One of these commenters stated that limiting the equipment permissible under the exception would hamper patient access to care and immediate diagnosis. This commenter stated that any DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and stated that safeguards to address potential risks of program or patient abuse from the use of such equipment are already built into that exception. The other of these commenters offered that, provided that fair market value is paid, a licensee physician should be able to use available advanced imaging, radiation therapy, laboratory, or other equipment.

In contrast, two commenters supported our proposal to limit the scope of the exception for timeshare arrangements to those arrangements that do not include the use of radiation therapy equipment, and another supported our proposal to prohibit the use of advanced imaging equipment. A different commenter urged us to prohibit the furnishing of physical therapy services on the premises protected by the new exception.

Response: We decline to remove from the exception finalized at §411.357(y) the requirement that the equipment covered by the timeshare arrangement is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other

than equipment used to perform CLIA-waived laboratory tests). As discussed in the preamble to the proposed rule and elsewhere in this section, the purpose of the exception for timeshare arrangements is to improve access to care and outcomes for our beneficiaries. In the case of radiation therapy equipment, we do not believe that it is necessary to include the use of such equipment under the exception to improve access to care. Radiation therapy equipment generally is not portable. Thus, any radiation therapy equipment that could be included in a timeshare arrangement would already be available to patients in the community. Including it in a timeshare arrangement would merely permit a physician to bill for the services that are already available to his or her patients from the hospital or physician organization granting the physician permission to use the equipment. As to advanced imaging equipment and laboratory equipment, we are not convinced and the commenter provided no proof that excluding such equipment from the scope of a protected timeshare arrangement would hamper access to care or delay a patient's diagnosis.

We also disagree with the first commenter's statement that DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and, therefore, the safeguards built into that exception are sufficient to address any risk of program and patient abuse. Other exceptions, such as the exceptions for bona fide employment at §411.357(c) and personal service arrangements at §411.357(d), may be available to protect referrals from the physicians in a group practice to the group. Further, not every physician organization that would bill for services furnished using premises and equipment under a timeshare arrangement will qualify as a "group practice" and have access to the in-office ancillary services exception.

We do not believe that it is necessary at this time to prohibit additional types of equipment under a timeshare arrangement, including equipment that is used to furnish physical

therapy services. As discussed in the response to a previous comment, we are finalizing the requirement that the equipment covered by a timeshare arrangement is not used to furnish DHS other than those incidental to the patient's E/M visit and furnished contemporaneously with that visit. To be protected under the exception, physical therapy services furnished using timeshare equipment must be incidental to the patient's E/M services and furnished at the time of the evaluation and management service to which they are incidental. We question whether it would be medically necessary for a patient to receive an E/M service at the time of each physical therapy visit. Moreover, we doubt that a physician furnishes an E/M service prior to each physical therapy session, which would be necessary to satisfy the requirement at final §411.357(y)(4).

Finally, we note that parties may use the existing exceptions for the rental of office space at §411.357(a) and the rental of equipment at §411.357(b), which include different safeguards against program and patient abuse, if they wish to include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests) in their arrangements.

Comment: Several commenters requested that we not require that equipment be located in the office suite where E/M services are furnished, suggesting that such a requirement could limit access to needed care, as an office suite may not adequately accommodate the equipment necessary to furnish DHS. One of these commenters noted that permitting the use of equipment in the "same building" where the E/M services are furnished is consistent with the requirements of the in-office ancillary services exception. This commenter suggested that, as an additional safeguard, where there are two licensed locations (for example, an office suite with E/M services and a room in the same building with equipment and DHS), CMS could require that the two locations be included in a single arrangement and used on identical schedules.

Response: We do not wish to impose restrictions that hinder the usefulness of the exception for ensuring access to needed care, but we must include requirements sufficient to guard against program or patient abuse when utilizing the Secretary's authority under section 1877(b)(4) of the Act. We agree that the usefulness of the exception for timeshare arrangements would be enhanced if we do not limit the location of the equipment to the office suite where E/M services are furnished to the patient. Accordingly, we are revising the requirement regarding the location of the equipment covered by the timeshare arrangement to require instead that the equipment is located in the same building as the office suite where the E/M services are furnished to the patient. To offset any potential increased risk of program or patient abuse due to this expansion of the exception, we are adopting the commenter's suggestion to include in the exception a requirement that all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. A requirement that the use of the premises where E/M services are furnished and the use of the premises where DHS are furnished must be included in a single arrangement would be superfluous because the exception would not protect premises used solely or predominantly for the furnishing of DHS. An arrangement to use premises, equipment, personnel, items, supplies, or services for the furnishing of DHS would satisfy the requirements of the new exception for timeshare arrangements only if the arrangement also includes permission to use the premises, equipment, personnel, items, supplies, or services predominantly for the furnishing of E/M services.

Comment: Three commenters urged us not to limit compensation methodologies or prohibit per-unit of service compensation for timeshare arrangements, stating that, in light of the substantial protections of the other requirements of the exception, a limitation on compensation methodologies is unnecessary and burdensome. Another commenter sought clarification

regarding whether the limitation on compensation formulas in the exception would effectively require block lease arrangements. The commenter stated that block lease arrangements are generally not conducive to either the licensor's or the licensee's delivery of services to their respective patients and recommended that we not require block lease arrangements.

Response: We are adopting our proposal to exclude from new §411.357(y) any timeshare arrangements that incorporate compensation formulas based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We are using the authority at section 1877(b)(4) of the Act to establish this exception. Because that authority permits only those exceptions that present no risk of program or patient abuse, we are protecting under new §411.357(y) only those timeshare arrangements that are based on other forms of compensation, such as those using flat-fee or time-based formulas. Timeshare arrangements that are based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. By way of example, we believe that a per-patient compensation formula could incentivize the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used. Similarly, a compensation formula that uses services as the unit of measure (for example, a per-CPT code compensation formula) could incentivize the timeshare grantor to refer sicker patients or patients with a likely need for DHS to the party using the timeshare, regardless of the preferences or best interests of the patients, because the grantor will receive a payment for each service furnished in the timeshare premises or using the timeshare equipment.

We recognize that many timeshare arrangements include compensation formulas that are set as a pre-determined amount for each hour, half-day or full-day spent using the premises, equipment, personnel, items, supplies, or services that are covered under the arrangement. We do not believe such compensation formulas raise the same risks as formulas that result in a payment to the party that provides the timeshare premises, equipment, personnel, items, supplies, or services each time that party refers a patient to the party using the timeshare. Under time-based compensation formulas, the “usage” fee is paid regardless of the number of patients referred by the timeshare grantor or the number of services furnished to such patients (or any other patients). We do not wish to call into question non-abusive timeshare arrangements with time-based compensation terms. Therefore, we are finalizing the requirement at §411.357(y)(6)(ii) to require that compensation under a timeshare arrangement is not determined using a formula based on per-unit of service fees, and we expressly do not prohibit compensation using a formula that is time-based (for example, per-hour or per-day). We are not prescribing a minimum amount of time per unit for compensation that utilizes a time-based formula and we remind readers that a compensation formula based on per-unit of service “usage” fees is prohibited under the exception only to the extent that such fees reflect services furnished to patients referred by the party granting permission to use its premises, equipment, personnel, items, supplies, or services to the party that receives such permission.

Although not addressed by any commenter, we are also aware of the recent D.C. Circuit decision in Council for Urological Interests v. Burwell, 790 F.3d 212 (D.C. Cir. 2014), which addressed the prohibition on per-click leasing arrangements with respect to the rental-equipment exception found in §411.357(b)(4)(ii)(B). We established this prohibition in the FY 2009 IPPS final rule using our authority under section 1877(e)(1)(B)(vi) of the Act, which requires an equipment lease to meet such other requirements as the Secretary may impose by regulation as

needed to protect against program or patient abuse in order for that lease to qualify for the exception for the rental of equipment. In the same rule, we also discussed certain legislative history contained in a House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report stated that--

The conferees intend that charges for space and equipment leases may be based on . . . time-based rates or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period. (H.R. Rep. No. 103-213, at 814 (1993).)

We noted in the FY 2009 IPPS final rule that CMS had previously interpreted this legislative history as indicating a view that per-click leases do not run afoul of section 1877(e)(1)(B)(iv), but we then stated that this language could also be interpreted as suggesting the Congress's disapproval of per-click leases. We explained, though, that our prohibition on per-click leasing arrangements was ultimately based on our authority to promulgate "other requirements" under section 1877(e)(1)(B)(vi) of the Act, and not on an interpretation of section 1877(e)(1)(B)(iv) of the Act.

In the Council for the Urological Interests case, the Court agreed with CMS that it had the authority to prohibit per-click leasing arrangements under section 1877(e)(1)(B)(vi) of the Act. The Court concluded that—

The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. (Council for Urological Interests, 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report

merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. *See id.* at 222 (explaining that the legislative history “simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv)] does not preclude per-click leases” and “[n]othing in the legislative history suggests a limit on [CMS’s] authority” to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act).

The Court concluded, however, that CMS’s revised interpretation of the House Conference Report was arbitrary and capricious, and it remanded the case to the agency to permit a fuller consideration of the legislative history. As previously noted, we are considering options as to how to comply with the court’s ruling.

Nonetheless, our current decision to prohibit per-unit of service compensation formulas under §411.357(y) is not affected by the Court’s decision in Council for Urological Interests. As explained, the Court did not hold that the House Conference Report requires us to allow per-click arrangements; to the contrary, the Court upheld our authority to prohibit per-click arrangements where we determine that such a prohibition is necessary to protect against program or patient abuse. (See Council for Urological Interests, 790 F.3d at 219-22.) Thus, we possess the authority to exclude timeshare arrangements that use a compensation formula based on per-unit of service fees from the new exception at §411.357(y), and we employ that authority here to ensure that the new exception will not pose a risk of program or patient abuse, as section 1877(b)(4) of the Act requires.

Comment: One commenter recommended that CMS allow the space that is used on a timeshare basis to be used as a provider-based department when it is not licensed to a physician. The commenter stated that this would allow hospitals to use its property and personnel more efficiently than currently allowed.

Response: The commenter's recommendation is outside the scope of this regulation.

Summary of the exception for timeshare arrangements as finalized at §411.357(y)

After careful consideration of the comments we received in response to the proposed exception, we are finalizing the exception for timeshare arrangements at §411.357(y) with the following modifications: (1) regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and: (i) a hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment covered by the timeshare arrangement may be in the same building (as defined at §411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises.

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). In the proposed rule, we proposed 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 also proposed to revise §411.353(g) to include reference to the new regulatory exceptions for payments to a physician to employ an NPP and timeshare arrangements that we proposed 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 for the same referring physician. Given these safeguards, we believe that the proposed revision poses no risk of program or patient abuse. We are finalizing our proposed revision to the special rule at §411.353(g).

The following is a summary of the comments we received.

Comment: The vast majority of commenters on this issue supported our proposal to allow all parties up to 90 days to obtain required signatures, regardless of whether the failure to obtain the signatures was inadvertent or not inadvertent. Several commenters requested that we remove the provision at §411.353(g)(2) that limits the use of the temporary noncompliance rule to once every 3 years for the same referring physician.

Response: We appreciate the commenters' support, and we are finalizing our proposal. However, we decline to remove the limitation on the use of the special rule to once every 3 years for the same physician. The signature requirement of certain compensation exceptions is statutory, and we believe that the requirement plays a role in preventing fraud and abuse. Among other things, the signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement. Requiring parties to sign an arrangement encourages parties to monitor and review financial relationships between DHS entities and physicians. In contrast, permitting parties to make frequent use of the special rule for noncompliance with signature requirements would not incent parties to exercise diligence with our rules. (See 73 FR 48707). We believe that repeated use of the special rule (that is, use more than once in a 3-year period) for the same physician may pose a risk of program or patient abuse.

Comment: One commenter requested clarification that the temporary noncompliance provision can be used more than once every 3 years for different physicians within the same group practice. According to the commenter, a party should be permitted to use the temporary noncompliance provision for an arrangement with a group practice for the services of one physician without precluding the party from using the temporary noncompliance provision within 3 years for another arrangement with the same group practice involving the services of a different physician.

Response: The “stand in the shoes” provisions at §411.354(c) determine whether a party may use the rule at §411.353(g)(1) more than once in 3 years for physicians associated with a physician organization. Assume a physician organization consists of 2 non-titular owners (Drs. A and B), and that a DHS entity enters into a compensation arrangement with the physician organization for the services of Dr. A on January 1, 2014.

The compensation arrangement with the physician organization is deemed to be a compensation arrangement with Dr. A and a compensation arrangement with Dr. B. If the parties do not sign the arrangement until February 15, 2014, but the arrangement otherwise satisfies the requirements of §411.353(g), the DHS entity may bill the program for DHS performed as a result of referrals by both Dr. A and Dr. B for the period from January 1, 2014 through February 14, 2014. That is to say that the special rule at §411.353(g) affords the DHS entity protection for referrals from each of the physicians who stand in the shoes of the physician organization. For precisely this reason, however, if the DHS entity enters into a different arrangement with the physician organization on March 1, 2015 for Dr. B’s services, and the parties do not sign the arrangement until May 1, 2015, the entity may not rely on the rule at §411.353(g) for either Dr. A or Dr. B for the period of March 1, 2015 through April 30, 2015. The entity already made use of the special rule for Dr. A and Dr. B’s referrals from January 1, 2014 through February 14, 2014. On the other hand, if the DHS entity entered into direct compensation arrangements with Drs. A and B (that is, arrangements with the physicians as opposed to arrangements with the physician organization), then the DHS could use the rule at §411.353(g) to protect referrals from Dr. A for the period from January 1, 2014 through February 14, 2014, and to protect referrals from Dr. B for the period from March 1, 2015 through April 30, 2015.

Comment: According to two commenters, a contract can be binding under State law even if it is missing the signature of one or more parties. The commenters urged CMS to adopt a similar rule for the physician self-referral law. Specifically, the commenters requested that CMS deem an arrangement to be signed, for the purposes of the physician self-referral law, even if one or more of the parties did not sign the arrangement, as long as the agreement is binding under State law. Another commenter asked CMS to establish that clear assent of the parties as to the terms of the arrangement is sufficient to satisfy the signature requirement.

Response: As noted elsewhere in this section, State contract law principles do not determine compliance with the physician self-referral law. The commenters' suggestion illustrates a problem with relying exclusively on State law principles, namely that the requirements for a contract to be enforceable under State law may differ substantively from the requirements of the physician self-referral law. By statute, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements require an arrangement to be signed "by the parties." (See section 1877(e) of the Act.) The commenters' suggestion that an arrangement should be deemed to comply with the signature requirement if one or more of the parties have not signed the arrangement is inconsistent with the plain language of the statute. In addition, as noted elsewhere in this section, we believe that the requirement that the parties sign an arrangement plays a role in preventing fraud and abuse. In this context, it is not enough that the course of conduct between the parties could support an inference of assent to the terms. Rather, a signature is necessary to provide a written record of the assent of the parties to the arrangement.

Comment: One commenter requested clarification as to what would satisfy the signature requirement of various compensation exceptions. The commenter specifically asked whether any of the following would satisfy the requirement that an arrangement be signed by the parties:

an electronic signature; a typed name; the name of the sender in the “from” line of an e-mail; the signature of the maker of a check; and the signature of a person endorsing a check. Another commenter asked CMS to explicitly allow electronic signatures. A third commenter suggested that State law principles should determine what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As noted elsewhere in this section, State law principles do not determine whether a party complies with the physician self-referral law, including compliance with the signature requirement. Nevertheless, parties may look to State law and other bodies of relevant law, including Federal and State law pertaining to electronic signatures, to inform the analysis of whether a writing is signed for the purposes of the physician self-referral law. Given evolving technologies, we are concerned that a prescriptive statement on our part regarding electronic signatures may unduly limit parties’ ability to comply with the physician self-referral law in the future.

We decline to state whether the examples provided by the commenter comply with the signature requirement for the following reasons: First, the exceptions require the arrangement to be signed by the parties. Even a document bearing the handwritten signature of one of the parties will not satisfy this requirement if the document, when considered in the context of the collection of documents and the underlying arrangement, does not clearly relate to the arrangement. Second, the intent of the party purportedly “signing” the standalone document is not clear in certain examples provided. Third, we are concerned that, by judging the examples in isolation from their context, we might unduly narrow parties’ ability to comply with the signature requirement. In sum, whether an arrangement is signed by the parties depends on the facts and circumstances of the arrangement and the writings that document the arrangement.

After careful consideration of the comments, we are finalizing our proposal to remove the distinction between inadvertent and not inadvertent failure to obtain a signature at §411.353(g). Under the final regulation, all parties have 90 days to obtain missing signatures. The regulation, as finalized, continues to limit the use of §411.353(g) by an entity to once every 3 years for a particular physician. At this time, we believe that this limitation is necessary to prevent 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 the 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 website 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 OPPTS/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 website 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, to avail itself of the applicable exception.

a. Preventing Conflicts of Interest: Public Website and Public Advertising Disclosure Requirement (§411.362(b)(3)(ii)(C))

Following publication of the CY 2011 OPPTS/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 website 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 website 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 website and advertising disclosure requirements to be prescriptive requirements for the inclusion of specific wording in an undefined range of communication. Accordingly, we proposed 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 website 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 Website and in any Public Advertisement, available on our website at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

For the public website disclosure requirement, we proposed to amend existing §411.362(b)(3)(ii)(C) to list examples of the types of websites that do not constitute a "public

website for the hospital.” We proposed to revise §411.362(b)(3)(ii)(C) to specify that a “public website for the hospital” does not include certain types of websites, even though limited information about the hospital may be found on such websites. For example, we do not consider social media websites to be “public websites 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 website, posting a video, or posting messages) via a social media website should be construed as a website that is “for the hospital,” given that the website 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 website, such as the hospital’s history, leadership and governance structure, mission, and a list of staff physicians. We also proposed to specify at §411.362(b)(3)(ii)(C) that a “public website 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 websites that do not constitute a “public website for the hospital” is not exhaustive. We recognize the difficulty in identifying every type of website that either currently exists or may emerge as technology develops that would not require a disclosure statement. We solicited public comments on whether our proposed examples are appropriate given the statutory language and whether we should include different or additional examples of websites in the list. We also solicited public comment on whether, in the alternative, we should provide an inclusive definition of what would be considered a “public

website for the hospital” and, if so, we solicited recommendations for such a definition. Finally, we note that, even if a website does not constitute a public website 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 proposed 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 proposed 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 proposed to define “public advertising for the hospital,” for the 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 proposed 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 proposed 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 sought 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 OPPI/ASC final rule with comment period, commenters stated 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 the proposed rule, we clarified 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 proposed to clarify the types of statements that constitute a sufficient statement of physician ownership or investment. Specifically, we proposed 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 sought public comment on our proposed revision to the public website and advertising disclosure requirements and on our proposed examples of language that would satisfy that standard. We also invited 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 OPPI/ASC final rule with comment period, that the disclosure should be located in a conspicuous place on the website 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 website. We did not propose to prescribe a specific location or font size for disclosure statements on either a public website 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 website 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 website 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 sought public comment on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

We are finalizing without modification our proposals regarding the public website and public advertising disclosure requirement at §411.362(b)(3)(ii)(C). The following is a summary of the comments we received.

Comment: A few commenters largely supported our proposed clarifications and regulations that articulate our existing policy concerning the public website and public advertising disclosure requirements. The commenters agreed that our proposed examples of statements that would constitute sufficient disclosure of physician ownership or investment interest demonstrate an appropriate approach to implementing the disclosure requirements.

Response: We appreciate the commenters' support. We are finalizing our proposal 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, as well as our proposed examples of language that would satisfy that standard as specified in the proposed rule (80 FR 41924). We note that our goal in proposing the examples of sufficient disclosure statements was to articulate a common sense understanding of what types of statements would satisfy the requirements.

Comment: One commenter supported our proposal to amend §411.362(b)(3)(ii)(C) to

specify examples of websites that, consistent with our existing policy, would not constitute “public websites for the hospital,” and therefore, would not require a disclosure of physician ownership or investment. However, the commenter requested that we revise the phrase “social media websites” in proposed amended §411.362(b)(3)(ii)(C) to read as “social media or networking websites” and that we include in the regulation specific examples of social media or networking websites.

Response: We are finalizing our proposal, without revision, to amend §411.362(b)(3)(ii)(C) to specify that a public website for the hospital does not include, by way of example: Social media websites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges. We are not persuaded to explicitly include “networking websites” in §411.362(b)(3)(ii)(C). We believe that it is commonly understood that networking websites are one form of social media and that our discussion of social media websites in the proposed rule is broad enough to include networking websites (80 FR 41924). We do not believe that additional guidance is necessary. Furthermore, we are hesitant to identify specific names of websites, even as examples, given the pace at which technology develops.

Comment: One commenter supported our specific proposal at §411.362(b)(3)(ii)(C) to exclude electronic patient payment portals and electronic patient care portals from qualifying as public websites for the hospital, because, according to the commenter, disclosing through either type of portal would not meet the disclosure requirement’s purpose of providing ownership information to the general public.

Response: We appreciate the commenter’s support for our proposal to exclude such portals from qualifying as a “public website for the hospital.” We agree with the commenter’s reasoning, and are finalizing the revisions as proposed.

Comment: One commenter supported our proposed definition of “public advertising for

the hospital” at §411.362(a), particularly our clarification in the definition that the advertisement must be “primarily intended to persuade individuals to seek care at the hospital.” The commenter also supported our proposed list of examples that, consistent with our existing policy, would not constitute “public advertising for the hospital” and therefore would not require disclosure of physician ownership or investment. However, the commenter urged CMS to add “search engine results” and “online listings of area hospitals” to our proposed list of examples given that, according to the commenter, an individual likely would not make a medical decision based on the limited information provided through either means of communication.

Response: We are finalizing our proposal, without revision, to add our proposed definition of “public advertising for the hospital” at §411.362(a). We are not persuaded to add “search engine results” and “online listings of area hospitals” to our list of examples. As we noted in the preamble to the proposed rule, our list of examples is not exhaustive, and a determination as to whether a specific communication qualifies as “public advertising for the hospital” will depend on the facts and circumstances of the communication (80 FR 41924). We also note that under our finalized policy the standard for whether a communication qualifies as “public advertising for the hospital” is, in part, whether the communication “is primarily intended to persuade individuals to seek care at the hospital” and not whether an individual is likely to make a medical decision based on the information provided in the communication. Finally, as we noted in our proposed rule, our existing regulations at §411.362(b)(3)(ii)(C) reference “public advertising” without explicitly specifying “for the hospital,” and we are finalizing our proposal to include the phrase “for the hospital” in our definition at §411.362(a) and in the disclosure requirement to conform our regulations to the statutory language.

Comment: One commenter requested that we identify a more definitive period of noncompliance for a physician-owned hospital’s failure to satisfy the public advertising

disclosure requirement. The commenter noted that, as to our example in the proposed rule concerning a physician-owned hospital's failure to include a disclosure in a monthly magazine advertisement, we stated that the period of noncompliance would "likely" be the applicable month of circulation despite the fact that the magazine may continue to be available (for example, in physician waiting rooms) for a period beyond the initial circulation.

Response: We are finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public website or public advertising disclosure requirements (80 FR 41925). We decline to identify a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising disclosure requirement. We believe that determining the period of noncompliance for a hospital's failure to disclose will depend on the specific facts and circumstances surrounding the hospital's public advertisement. We intended our example in the proposed rule to provide only general guidance and not to delineate a bright-line rule.

After careful review and consideration of the comments, we are finalizing our proposal, without revision, to amend §411.362(b)(3)(ii)(C) to specify that a public website for the hospital does not include, by way of example: Social media websites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges. We are finalizing our proposal, without revision, to add our proposed definition of "public advertising for the hospital" at §411.362(a). We are also finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public website or public advertising disclosure requirements (80 FR 41925).

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 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 OPPTS/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 stated 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 the 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 OPPTS/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 stated 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 stated that including only referring physicians in the definition of physician owner or investor for the 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 stated 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 the 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 proposed to revise our policy articulated in the CY 2011 OPPTS/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 the 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 sought 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 the purposes of establishing their baseline bona fide investment levels and the bona fide investment levels generally.

To support our proposal and implement the requirements of the statute, we proposed to amend our existing regulations to specify that, for the purposes of §411.362 (including for the 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 proposed to effectuate this change by establishing a definition of ownership or investment interest solely for the 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 proposed 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 also proposed 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) better align with the statutory definition of “physician owner or investor” in a hospital without unsettling long-standing definitions in our regulations. We solicited public comments 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 OPPTS/ASC final rule with comment period.

We solicited public comments on an alternate proposal that we believe also supports our

policy and, thereby, effectuates the statute's purpose. Specifically, we solicited public comments 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 invited public comments 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, in the proposed rule we recognized that some physician-owned hospitals may have relied on the position that was articulated in the CY 2011 OPPI/ASC final rule with comment period concerning non-referring physicians and the baseline bona fide investment level. If we finalized 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 proposed 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 stated that 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 solicited comments on how long we should delay the effective date. We also solicited comments 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.

The following is a summary of the comments we received.

Comment: Four commenters disagreed with the bona fide investment level proposal, citing a variety of reasons. For example, two commenters stated that requiring the inclusion of

ownership and investment interests held by non-referring physicians in the baseline bona fide investment level and every assessment of the bona fide investment level thereafter is inconsistent with the purpose of the physician self-referral law. One of these commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the bona fide investment levels would stifle physician investment in physician-owned hospitals and frustrate physician recruitment to communities served by physician-owned hospitals.

Another commenter asked us to refrain from finalizing the proposal until we can articulate the precise risk of fraud or abuse that excluding the ownership and investment interests held by non-referring physicians from the bona fide investment levels would have on the Medicare program. One commenter stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline bona fide investment level and every assessment of the bona fide investment level thereafter impermissibly expands the scope of the physician self-referral law because, according to the commenter, without a “referral,” a physician’s ownership or investment interest in an entity does not implicate the law and, thus, no applicable exception is needed. This commenter stated that we should create a special carve out for physician-owned hospitals that did not obtain a provider agreement until sometime after March 23, 2010, but by the December 31, 2010 deadline, and that these hospitals should include the ownership and investment interests held by all physicians, regardless of referral status, in the baseline bona fide investment level.

Response: We continue to believe that the revised policy articulated in the proposed rule is the only reading of the statute that fully accounts for all relevant provisions of law. We do not believe that we have the authority to continue implementing a policy that is inconsistent with the statute. Accordingly, we are finalizing our proposal, without revision, 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 she 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 the purposes of our regulatory definition of ownership or investment interest at §411.354). We also are finalizing, without revision, our proposed definition of “ownership or investment interest” in §411.362 to implement our revised policy.

Comment: One commenter stated that requiring the inclusion of the ownership and investment interests held by all physicians, regardless of whether each qualifies as a “referring” physician, is a more faithful interpretation of the statute than the policy that we articulated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72250). The commenter stated, however, that we should implement the statute in a different manner than the proposal set forth in the proposed rule. Specifically, the commenter stated that all ownership and investment interests held by physicians as of March 23, 2010, should be included in a hospital’s baseline bona fide investment level regardless of whether each physician was referring as of that date, but that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the bona fide investment level thereafter. The commenter noted that in regulations governing provider agreements at §489.20(u) and (v), CMS chose to not require disclosure of physician ownership interests for any physician-owned hospital that does not have at least one referring physician.

Response: We agree with the commenter that the proposal better aligns with the statute than the policy articulated in the CY 2011 OPPS/ASC final rule with comment period. However, we disagree that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the bona fide investment level after March 23, 2010. We believe that the term “physician owner or

investor” as used in the bona fide investment level requirement has a singular, defined meaning and that the Congress provided guidance about that meaning through its broad definition of “physician owner or investor” at section 1877(i)(5) of the Act, which is supported by a harmonious reading of multiple statutory provisions. Further, as we noted in the proposed rule, if the term “physician owner or investor” was intended to include only referring physicians in the bona fide investment level requirement, such qualifying language would have been included in the statute, such as in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Although the commenter’s recommended approach would resolve the issue concerning pre-operational hospitals that we discussed in the proposed rule (80 FR 41925), we do not believe that the statute provides sufficient support for concluding that two separate standards can apply for calculating the baseline bona fide investment level and every bona fide investment level thereafter. Finally, as to the commenter’s statements regarding §489.20(u) and (v), the regulations that govern provider agreements and our regulations concerning the physician self-referral law are two distinct regulatory schemes. Although the regulations cited by the commenter mention physician-owned hospitals, we are bound by the provisions of the physician self-referral law.

Comment: One commenter requested that we clarify that a physician-owned hospital did not improperly calculate its baseline bona fide investment level by including the ownership and investment interests held by all physicians regardless of referral status.

Response: We confirm that a proper calculation of a physician-owned hospital’s baseline bona fide investment level includes the ownership and investment interests held by all physicians regardless of referral status.

Comment: Two commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline bona fide investment level

and the assessment of every bona fide investment level thereafter likely would cause financial hardship for any non-referring or retiring physicians who would need to sell their ownership interests at the current fair market value to allow a physician-owned hospital to comply with the new policy. The commenters also stated that physician-owned hospitals likely would have to restructure their governance, given the necessary ownership changes, and that such restructuring likely would be difficult and costly for the hospitals.

Response: We acknowledge the commenters' concerns regarding the potential effect that this policy may have on individual physician owners, as well as physician-owned hospitals. While we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

After consideration of the comments, we are amending our existing regulations to specify that, for the purposes of §411.362 (including for the 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 are establishing a definition of ownership or investment interest solely for the 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 are defining "ownership or investment interest" at §411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the final rule, 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. 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.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

a. 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. In our proposed rule, we highlighted certain provisions of the Affordable Care Act that grant the Secretary broad authority to test models implementing health care delivery and payment reform. (See 80 FR 41927-28.)

As noted in our proposed rulemaking, 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>.)

b. 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 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 three-part 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 Medicare Shared Savings Program or certain Center for Medicare and Medicaid Innovation-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 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.

c. Analysis of Comments

To help inform the APM Report and Gainsharing Report required under sections 101(e)(7) and 512(b) of MACRA, respectively, and to aid us in determining whether additional rulemaking or guidance is desirable or necessary, we solicited comments regarding the impact of the physician self-referral law on health care delivery and payment reform. On this subject, we specifically solicited comments regarding the "volume or value" and "other business generated" standards, but welcomed comments concerning any of our rules for determining physician compensation.

We received a number of thoughtful comments on the issues raised in the solicitation. We thank the commenters for their input, and we will carefully consider their comments as we prepare the reports to Congress required under sections 101(e)(7) and 512(b) of MACRA and determine whether additional rulemaking on these issues is necessary. We would like to note that our silence in this rule should not be viewed as an affirmation of any commenter's interpretations or views.

10. Technical Corrections

We have become aware that some of the manual citations listed in our regulations are no longer correct. We therefore proposed 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 proposed to modernize the regulatory text by changing "Web site" to "website" in §411.351,

definition of “list of CPT/HCPCS Codes”, §411.357(k)(2), (m)(2) through (m)(3), and (m)(5), §411.362(c)(2)(iv) through (v) and (c)(5), and §411.384(b). Lastly, we are removing the hyphen from “publicly-traded” at §411.356(a) and §411.361(d), and we are correcting a minor typographical error at §411.357(p)(1)(ii)(A).

After the proposed rule went on display, the term “website” was inadvertently changed to “Web site.” Our intention in the proposed rule was to change all instances of the term “Web site” to “website.” We are making this change in the final rule.

11. Comments Outside the Scope of This Rulemaking

Comment: We received several comments, including suggestions on policy changes that are outside the scope of this rulemaking. For example, one commenter requested revisions to the in-office ancillary services exception. Another commenter requested that we make regulatory protections for electronic health records permanent. We also received a few requests that the physician self-referral law be eliminated entirely. In addition, some commenters described their interpretations of various physician self-referral issues or asked questions about existing regulations.

Response: Although we appreciate the commenters taking the time to present these positions, these comments are beyond the scope of this rulemaking and are not addressed in this final rule with comment period. We express no view on these issues; our silence should not be viewed as an affirmation of any commenter’s interpretations or views. If these issues are addressed in the future, we will publish a notice of proposed rulemaking that will be open to public comment at that time. Finally, we refer readers to the final rule regarding our exception for electronic health records at §411.357(w), published December 27, 2013 (78 FR 78751).

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 Regulation

The private contracting/opt out provisions at section 1802(b) of the Act were recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 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 MAC. Section 106(a) of the 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 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 proposed 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 proposed 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 proposed to amend §§405.410(d), 405.435(d), and 405.445(b)(2) so that the term “carrier” is replaced with “Medicare Administrative Contractor”.

We received 13 comments on our private contracting/opt-out proposal.

Comment: Many commenters supported the proposed rule.

Response: We appreciate the commenters’ support.

Comment: One commenter proposed that the rule be modified to permit cancellation of opt-out (with a 30-day notice) any time after the physician’s or practitioner’s initial 2-year opt-out period concludes. The commenter stated that a physician who cancels opt-out and later chooses to opt-out again should be subject to another initial 2-year opt-out period. The

commenter contended that such a standard would be sufficient to prevent abuse without requiring the perpetual monitoring of opt-out renewal dates.

Response: We appreciate the comment, but note that the commenter's proposal is inconsistent with the requirements of section 106(a)(1) of MACRA. As noted earlier in this preamble, the MACRA amendments permit 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 to cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2-year opt-out period. The MACRA amendments changed the procedures for renewing the opt-out period; it now renews automatically unless we receive written notice requesting otherwise. The MACRA amendments, however, did not change the requirement that physicians and practitioners opt-out in 2-year intervals. Therefore, because MACRA does not provide any flexibility to cancel opt-out before the 2 year opt-out period actually ends, we are not modifying the rule based on this comment.

To effectuate the changes made by the MACRA, we are finalizing these provisions of the rule as proposed with the exception of minor editorial changes to §405.445. These changes clarify this section consistent with plain language principles but do not alter the meaning of the proposal.

P. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies.

Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and §411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In §411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§411.355(h)).

The definition of DHS at §411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at §411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. Most recently, on December 19, 2014, section 204 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113-295) was enacted and delayed the inclusion of these drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS. For purposes of the exception at §411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the CY 2010 PFS final rule with comment period (75 FR 73583), we do not believe any of these drugs are required for the efficacy of dialysis. Therefore, we have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Tables 90 and 91 of the CY 2015 PFS final rule with comment period (79 FR 67973-67975).

b. Response to Comments

We received three public comments relating to the Code List that became effective January 1, 2015.

Comment: All of the commenters requested the removal of two disposable negative pressure wound therapy (NPWT) codes, 97607 and 97608. The commenters stated that the definition of “referral” does not include services personally performed by the referring/ordering physician and that a typical patient provided with a disposal NPWT device will require significant clinical interaction from the physician to thoroughly clean a wound prior to application of such a device.

Response: We are aware that there are some circumstances under which these codes will not be considered therapy services. The codes in question are not considered therapy services when: (1) it is not appropriate to bill the service under a therapy plan of care; and (2) they are billed by practitioners/providers of services who are not therapists, such as physicians, CNSs, NPs and psychologists; or they are billed to MACs by hospitals for outpatient services which are performed by non-therapists. However, these and certain other codes can also be furnished as therapy services, specifically under a physical therapy, occupational therapy, or speech-language pathology plan of care in accordance with section 1861(p) of the Act. We note that determinations should be made on a case-by-case basis with respect to whether the physician self-referral law is implicated when using these codes. Please refer to the billing rules associated with these codes to avoid violating the physician self-referral law.

c. Revisions Effective for CY 2016

The updated, comprehensive Code List effective January 1, 2016, is available on our website at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 50 and 51 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2016. Tables 50 and 51 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in §411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in §411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 50 and 51. Comments will be considered if we receive them by the date specified in the “DATES” section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS definitions in §411.351.

TABLE 50: Additions to the Physician Self-Referral List of CPT¹/HCPCS Codes

CLINICAL LABORATORY SERVICES	
G0475	HIV combination assay
G0476	HPV combo assay CA screen
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES	
{No additions}	
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES	
72081	X-ray exam entire spi 1 vw
72082	X-ray exam entire spi 2/3 vw
72083	X-ray exam entire spi 4/5 vw
72084	X-ray exam entire spi 6/> vw
73501	X-ray exam hip uni 1 view
73502	X-ray exam hip uni 2-3 views
73503	X-ray exam hip uni 4/> views
73521	X-ray exam hips bi 2 views
73522	X-ray exam hips bi 3-4 views
73523	X-ray exam hips bi 5/> views
73551	X-ray exam of femur 1
73552	X-ray exam of femur 2/>
74712	Mri fetal snl/1st gestation
78265	Gastric emptying imag study
78266	Gastric emptying imag study
C9457	Lumason contrast agent
C9458	Florbetaben F18
C9459	Flutemetamol F18
G0297	LDCT for Lung CA screen
RADIATION THERAPY SERVICES AND SUPPLIES	
0394T	Hdr electrnc skn surf brchtyx

0395T	Hdr elctr ntrst/ntrev brchtx
77767	Hdr rdnel skn surf brachytx
77768	Hdr rdnel skn surf brachytx
77770	Hdr rdnel ntrstl/icav brchtx
77771	Hdr rdnel ntrstl/icav brchtx
77772	Hdr rdnel ntrstl/icav brchtx
C2645	Brachytx planar, p-103
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS	
{No additions}	
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES	
G0475	HIV combination assay
G0476	HPV combo assay CA screen

¹CPT codes and descriptions only are copyright 2015 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 51: Deletions from the Physician Self-Referral List of CPT¹/HCPCS Codes

CLINICAL LABORATORY SERVICES	
0103T	Holotranscobalamin
G0431	Drug screen multiple class
G0434	Drug screen multi drug class
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES	
{No deletions}	
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES	
72010	X-ray exam of spine
72069	X-ray exam of trunk spine
72090	X-ray exam of trunk spine
73500	X-ray exam of hip
73510	X-ray exam of hip
73520	X-ray exam of hips
73540	X-ray exam of pelvis & hips
73550	X-ray exam of thigh
RADIATION THERAPY SERVICES AND SUPPLIES	
0182T	HDR elect brachytherapy
77777	Apply interstit radiat inter
77787	HDR brachytx over 12 chan
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS	
{No deletions}	
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES	
90669	Pneumococcal vacc 7 val im

¹ CPT codes and descriptions only are copyright 2015 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

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.

In the CY 2016 PFS proposed rule (80 FR 41930 through 41937) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. PRA-related comments were received as indicated below under section IV.B.

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 52 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 52: 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. Information Collection Requirements (ICRs) Carried Over From the CY 2016 Proposed Rule

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 (MACs).

To be consistent with section 106(a), we revised 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 x \$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 written request to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 min each for a total of 10 hr. We also estimate that a medical secretary will perform this duty at \$32.24/hr for a total cost of \$322.40 (10 hr x \$32.24/hr).

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change. 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)

For a clinic that was billing as if it were provider-based to an IHS hospital as of April 7, 2000, and is now a tribally-operated clinic contracted or compacted under the ISDEAA, §§405.2462(d) and 405.2463(c)(4) provides that the clinic may seek to become certified as a grandfathered tribal FQHC. To become certified, an eligible tribe or tribal organization must submit an enrollment application (CMS-855A, OMB control number 0938-0685) and all required 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, will 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.*). We did not receive any public comments regarding the exempt information collection requirements and are finalizing the policy as proposed.

3. ICRs Regarding the Payment for RHC and FQHC Services (§405.2462)

Section 405.2462(g)(3) requires that RHCs report Healthcare Common Procedure Coding System (HCPCS) and other codes as required in reporting services furnished to a Medicare beneficiary during a RHC visit.

The ongoing burden associated with the requirements under §405.2462(g)(3) is the time and effort it will 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 some RHC billing staff will need training 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 the training 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 policy may not require any additional coding time since they are already capturing HCPCS coding in their billing or electronic health record systems. For those RHCs that are not already capturing HCPCS coding in their billing or electronic health record systems, they 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:

$$(8,964,208 \text{ Medicare claims in 2013} \times 3.5 \text{ min}) / 60 \text{ min} = 522,912.13 \text{ hr (aggregate)}$$

$$522,912.13 \text{ hr} / 4,000 \text{ RHCs} = 130.73 \text{ hr (per RHC)}$$

$$522,912.13 \text{ hr} \times \$26.68/\text{hr} = \$13,951,295.63 \text{ additional cost (aggregate)}$$

$$\$13,951,295.63 / 4,000 \text{ RHCs} = \$3,487.82 \text{ per RHC}$$

In deriving these figures, we analyzed claims data and RHC certification data maintained by CMS and used BLS wage data (see Table 52).

We did not receive any public comments regarding our proposed burden estimates. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016, to allow the MACs additional time to implement the necessary claims processing systems changes completely. The burden for the aforementioned requirements will be submitted to OMB for approval under control number 0938-1287 (CMS-10568).

4. ICRs Regarding Exceptions to the Referral Prohibition Related to Compensation Arrangements (§411.357)

Section 411.357 is revised to establish two new exceptions: (1) an exception to permit remuneration to independent physicians to assist in compensating nonphysician practitioners in the geographic service area of the hospital, FQHC, or RHC providing the remuneration, and (2) 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 clarified the writing requirements for compensation arrangements in §411.357(a), (b), (d), (e), (l), (p), and (r). The burden associated with these requirements is 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). Since financial arrangements are usually and routinely documented in writing as a standard good business practice, 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 exempt as a usual and customary business practice.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

5. ICRs Regarding the Physician Quality Reporting System (PQRS) (§414.90 and Section III.I. 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 (1) identifying applicable quality measures for which they can report the necessary information, (2) selecting a reporting option, (3) collecting the necessary information, and (4) 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.

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 (1) review the PQRS Measures List, (2) review the various reporting options, (3) select the most appropriate reporting option, (4) identify the applicable measures or measures groups for which they can report the necessary information, (5) review the measure specifications for the selected measures or measures groups, and (6) incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title along with a summary 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, select a reporting option, and select the measures on which to

report. If an eligible professional has received training, we believe this will take less time. CMS believes that 3 hr 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 \text{ hr} \times \$26.68/\text{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 reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down our burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

a. Burden for Reporting by Individual Eligible Professionals: 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 by OMB under control number 0938-0999. This rule does not revise either of these forms. We note that the claims-based reporting option is only available to individual eligible professionals and is not available for group practice reporting under the GPRO.

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 will take approximately 2.25 min (0.25 min x 9) to 108 min (12 min x 9) to perform all of the necessary steps.

At an adjusted labor rate of \$83.96/hr for a computer systems analyst, the per measure cost will range from \$0.35 [(\$83.96/hr / 60) x 0.25 min] to \$16.79 [(\$83.96/hr / 60) x 12 min], with a median cost of \$2.45 [(\$83.96/hr / 60) x 1.75 min]. To report nine measures we estimate that the cost will range from \$3.15 (\$0.35 x 9) to \$151.11 (\$16.79 x 9), with a median cost of \$22.05 (\$2.45 x 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 will range from 13.5 min (0.25 min per measure x 9 measures x 6 cases per measure) to 648 min (12 min per measure x 9 measures x 6 cases per measure), with a median burden of 94.5 min (1.75 min per measure x 9 measures x 6 cases). We also estimate that the cost will 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 53 summarizes the range of total annual burden associated with eligible professionals using the claims-based reporting mechanism.

TABLE 53: 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

We received comments related to the estimates in Table 53 and how they relate to reporting using other reporting mechanisms, such as the registry, EHR, and QCDR reporting mechanisms. Please note that the figures in Table 53 only reflect our estimates for reporting via the claims-based reporting mechanism, and not the other PQRS reporting mechanisms.

b. Burden for Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and QCDR-based Reporting Mechanisms

There is no additional time for individual eligible professionals or group practices to report data to a qualified registry since eligible professionals and group practices opting for

qualified registry-based reporting or the use of a QCDR will 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.

Eligible professionals and group practices 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 is 5 min per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above, Table 54 summarizes the total annual burden associated with eligible professionals and group practices 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 or group practice would not be required to submit this data to CMS since the qualified registry or QCDR would perform this function on their behalf.

TABLE 54: 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

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

c. Burden for 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 (1) review the quality measures on which we will be accepting PQRS data extracted from EHRs, (2) select the appropriate quality measures, (3) extract the necessary clinical data from his or her EHR, and (4) 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 hr to obtain. Once an eligible professional or eligible professional in a group practice has an account, he or she needs to extract the necessary clinical data from his or her EHR and submit the 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 for the eligible professional or group practice to submit data on quality measures should be minimal since the information should already reside in the eligible professional's or group practice's EHR.

In this rule, group practices with 100 or more eligible professionals must report on CAHPS for PQRS (the survey is approved by OMB under control number 0938-1222, CMS-10450). Therefore, a group practice of 100 or more eligible professionals is 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 55 summarizes the total annual burden 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 since the EHR product would perform this function on the eligible professional's behalf.

TABLE 55: 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

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

d. Burden for 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. 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).

We estimate that the self-nomination process will require 2 hr for a group practice to review the PQRS GPRO and decide whether to participate as a group or individually. We also estimate an additional 2 hr for a group practice to draft their 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 (BLS occupation: billing and posting clerks) has an adjusted labor rate of \$26.68/hr. By projecting 6 hr (per group practice) for the self-nomination process, we estimate a total of 3,000 hr (500 group practices x 6 hr) at a cost of \$80,040 (3,000 hr \$26.68/hr).

The burden associated with the group practice reporting requirements under the GPRO mechanism is the time and effort for group practices to submit the quality measures data. For physician group practices, this is the time for the physician group to complete the web interface. We believe that the burden associated with using the GPRO web interface is comparable to that of using the Performance Assessment Tool (PAT). The PAT was the precursor to the current PQRS GPRO Web Interface and was used in several physician pay for performance demonstrations. The information collection components of the PAT have been reviewed by OMB and are approved under 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 using the PAT. 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 \$6,632.84 (79 hr x \$83.96/hr). In aggregate, we estimate 39,500 hr (500 group practices x 79 hr) and \$3,316,420 (39,500 hr x \$83.96/hr).

Based on the assumptions discussed above, Table 56 summarizes the total annual burden associated with the group practice reporting of quality measures.

TABLE 56: 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

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

e. Total Estimated Burden of this Information Collection Requirement for 2016

It is difficult to accurately estimate the total annual burden associated with the submission of the quality measure data for the PQRS. Since there are a number of reporting mechanisms that eligible professionals can use to report the PQRS measures, it may be more burdensome for certain practices to use a particular reporting mechanism to report their PQRS

measures and/or electronic prescribing measures than others. As indicated, 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 was new for the 2014 PQRS. Therefore, Table 57 provides a range of estimates for individual eligible professionals or group practices using the claims, qualified registry, or EHR-based reporting mechanisms. The upper range represents the sum of the estimated maximum hours and cost per eligible professional from Tables 53, 54, and 55. We are updating our currently approved figures for the upper range of estimates provided in Table 57. Changes to the estimated burden for 2016 are due to updated BLS wage figures, inclusion of benefits and overhead allowance, a change in participation estimates for eligible professionals using the qualified registry (QCDR) and EHR-based reporting mechanisms and a change in reporting requirements in the PQRS for the 2018 PQRS payment adjustment.

TABLE 57: Total Burden for Eligible Professionals and/or Group Practices Using the Claims, Qualified Registry or QCDR, 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
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 burden for group practices, Table 58 reiterates the burden (see Table 56) to participate in PQRS under the group practice reporting option using the GPRO web interface.

TABLE 58: Total Burden 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

The requirements and burden estimates will be submitted to OMB under control number 0938-1059 (CMS-10276).

6. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§414.94)

Consistent with section 1834(q) of Title XVIII of the Act (as amended by section 218(b) of the PAMA), we have adopted specific requirements for the development of appropriate use criteria (AUC) that can be specified under §414.94 as part of the Medicare program. PLEs that use processes that meet certain requirements and want to be recognized as qualified PLEs for the purpose of this section may apply to CMS.

Applications must be submitted electronically and demonstrate how the organization's processes for developing AUC meet the requirements specified in §414.94(c)(1) which include: a systematic literature review of the clinical topic and relevant imaging studies; led by at least one multidisciplinary team with autonomous governance; a process for identifying and resolving conflicts of interest of team members, the PLE and any other party participating in AUC development or modification; publication of individual appropriate use criterion on the qualified PLE's website; identification of AUC that are relevant to priority clinical areas; 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 (at least annually); a process for developing, modifying or endorsing AUC publicly posted on the entity's website; and the disclosure of external parties involved in the AUC development process.

To be identified as a qualified PLE by CMS, organizations must meet the definition of PLE, and demonstrate adherence to the requirements in their application for CMS review and use the application process identified in §414.94(c)(2) of the regulations. Applicant PLEs must submit applications documenting adherence to each AUC development requirement; applications will be accepted annually by January 1; all qualified PLEs approved in each year will be posted

to the CMS website by June 30; and all qualified PLEs must re-apply every 5 years and applications must be submitted by January 1 during the 5th year after the qualified PLE's most recent approval date. If a qualified PLE is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

The one-time burden associated with the requirements under §414.94(c)(2) is the time and effort it will take each of the 30 organizations that have expressed interest in developing AUC to compile, review and submit documentation demonstrating adherence to the 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 hours at \$67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hours at \$99.68/hr for a medical and health services manager to review and approve the submission, and 5 hours at \$187.48/hr for a physician to review and approve the submission materials. In this regard, we estimate 30 hours per submission at a cost of \$2,783.40 per organization. In aggregate, we estimate 900 hours (30 hr x 30 submissions) at \$83,502 (\$2,783.40 x 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified PLEs 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 PLEs must re-apply every 5 years. Therefore in years 5-10, 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 PLEs will be able to make modifications to their original application which should result in a burden of 10 hours at \$67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at \$99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hours at \$187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of \$1,391.70 per organization. In aggregate, we estimate 450 hours (15 hr x 30 submissions) at \$41,751 (\$1,391.70 x 30 submissions).

Section 414.94(f)(3) provides that CMS may terminate the qualified status of a PLE if it finds that the PLE is not adherent to the requirements in §414.94(c). In this instance the PLE would need to re-qualify to reinstate their status. The requalification requirements are associated with an administrative action. In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2) and (c), the associated burden is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We also estimate that the requalification process would apply to fewer than ten respondents per year. Consequently, the information collection requirements are also exempt under 5 CFR 1320.3(c) of the Paperwork Reduction Act's implementing regulations.

While we received public comments (see below) regarding our proposed requirements and burden, we have considered the comments and are adopting the proposed provisions with minimal changes. The requirements and burden will be submitted to OMB under control number 0938-New (CMS-10570).

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the fifth year of approval will receive a determination prior to the start of the qualified PLE's sixth year. Therefore, the cycle of approval for qualified PLEs is every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017.

Year 2 = July 2017 to June 2018.

Year 3 = July 2018 to June 2019.

Year 4 = July 2019 to June 2020.

Year 5 = July 2020 to June 2021 (reapplication is due by January 1, 2021).

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if qualified PLEs are not maintaining compliance with our requirements for AUC development, we may terminate their qualified status.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS website.

Response: At least for the first round of applications for qualified PLEs, we will not be

making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient, or necessary.

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 CPC initiative and the Medicare EHR Incentive Program whereby CPC practice sites are required to report at least nine clinical quality measures across 3 domains in accordance with the requirements established by the CPC initiative, which also satisfies the CQM requirements of the Medicare EHR Incentive Program. The aligned reporting between CPC and the Medicare EHR Incentive Program also allows first year EPs participating in the Medicare EHR Incentive Program to satisfy the CQM requirements of the Medicare EHR Incentive Program through successfully meeting CPC CQM reporting requirements. 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 Annual Burden Estimates

TABLE 59: 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	32.24	-29,016
405.445(a)	0938-0730 (CMS-R-234)	60	60	10 min	10	32.24	322
405.2462(g)(3)	0938-1287 (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 x 6)	5.2 hr (5 hr + 12 min))	5,528,488	varies (see Table 53)	364,021,000
		212,000 (qualified registry-based and QCDR-based reporting)	212,000	8.083 hr	1,713,596	varies (see Table 54)	83,157,000
		50,000 (EHR-based reporting)	50,000	9	450,000	varies (see Table 55)	23,462,000
		500 (GPRO web interface)	500	85	42,500	varies (see Table 56)	3,396,460
414.94(c)(1) and (2)	0938-1288 (CMS-10570)	30	30	5 hr	150	187.48	28,122
				5 hr	150	99.68	14,952
				20 hr	600	67.38	40,428
Total	--	--	--	--	8,257,506	--	488,042,564

D. Submission of PRA-Related Comments

We have submitted a copy of this rule's information collection and recordkeeping requirements to OMB for review and approval. The requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' website 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 identify the rule (CMS-1631-FC) and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: 202-395-5806 OR

E-mail: OIRA_submission@omb.eop.gov.

ICR-related comments must be received on/by December 29, 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. Waiver of Proposed Rulemaking and Waiver of Delay in Effective Date

A. PFS provisions

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures.

The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on all of these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians and

non-physician practitioners during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. In general, we assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By reviewing the AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. We also note, as explained in section II.A. of this final rule, that we finalized a new process for establishing values for new, revised and potentially misvalued codes in the CY 2015 final rule. In rulemaking to adopt this new process, we assessed the trade-offs involved and determined that, on balance, we should move to a process that involves greater transparency and stakeholder input. We also noted our desire to work with the RUC to receive recommendations for new, revised and potentially misvalued codes within a timeframe to support our new process. CY 2016 is a transition year for this new process, and we anticipate this will be the last year we will need to establish payment for these codes on an interim basis, with the infrequent exception for codes that describe wholly new services. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of

these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes until notice and comment procedures could be completed.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.H. of this final rule with comment period discusses our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the services identified as potentially misvalued codes, and because, as noted earlier, this is the transition year for the new process for establishing values for new, revised and potentially misvalued codes that we finalized in the CY 2015 final rule, it is impracticable for CMS to provide for notice and comment regarding specific revisions for all codes prior to publication of this final rule with comment period. 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 in order to facilitate continued payment for most services for which we do not receive RUC 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 RUC recommendations in time to propose values.

We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the AMA RUC, on an interim final basis for CY 2016. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS. Implementing the changes on an interim basis allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period makes payment and policy changes under the Medicare PFS and makes 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 final rule with comment period rule also makes changes to Part B payment policy and other Part B related policies.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate, as discussed in this section, that the PFS provisions included in this final rule with comment period 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

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 website at <http://www.sba.gov/content/table-small-business-size-standards> (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this final rule with comment period 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 604 of the RFA. For purposes of section

1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule with comment period 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 final rule with comment period 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 prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule with comment period; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule with comment period, we proposed 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 final rule with comment period. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period 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 final rule with comment period 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 repealed the previous statutory update formula and specified the update adjustment factors for calendar years 2015 and beyond.

We note that section 220(d) of the PAMA added a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. Section 1848(c)(2)(O)(iii) of the Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. We estimate the CY 2016 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.23 percent. Since this does not meet the 1 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE), payments under the fee schedule must be reduced by the difference between the target for the year and the estimated net reduction in expenditures (the “Target Recapture Amount”). As a result, we estimate that the CY 2016 Target Recapture Amount will produce a reduction to the CF of -0.77 percent.

To calculate the conversion factor for the year, we multiply the product of the current year conversion factor and the update adjustment factor by the budget neutrality adjustment, and then adjust that figure by the target recapture amount, if applicable. We estimate the CY 2016 PFS conversion factor to be \$35.8279, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under the MACRA, and the 0.77 percent target recapture amount required under Section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2016 anesthesia conversion factor to be \$22.3309, which reflect the same adjustments, with the addition of anesthesia-specific PE and MP adjustments.

TABLE 60: Calculation of the CY 2016 PFS Conversion Factor

Conversion Factor in effect in CY 2015		35.9335
Update Factor	0.5 percent (1.005)	
CY 2016 RVU Budget Neutrality Adjustment	-0.02 percent (0.9998)	
CY 2016 Target Recapture Amount	-0.77 percent (0.9923)	
CY 2016 Conversion Factor		35.8279

TABLE 61: Calculation of the CY 2016 Anesthesia Conversion Factor

CY 2015 National Average Anesthesia Conversion Factor		22.6093
CY 2016 RVU Budget Neutrality Adjustment	-0.02 percent (0.9998)	
CY 2016 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	-0.445 percent (0.99555)	
CY 2016 Target Recapture Amount	-0.79 percent (0.9923)	
CY 2016 Conversion Factor		22.3309

Table 62 shows the payment impact on PFS services of the proposals contained in this final rule with comment period. 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 62 (CY 2016 PFS Estimated Impact on Total Allowed

Charges by Specialty). The following is an explanation of the information represented in Table 62.

- 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 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 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 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 changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 62: CY 2016 PFS Estimated Impact on Total Allowed Charges by Specialty*

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
TOTAL	\$89,020	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	\$221	0%	0%	0%	0%
ANESTHESIOLOGY	\$1,970	0%	1%	-2%	0%
AUDIOLOGIST	\$61	0%	-1%	1%	-1%
CARDIAC SURGERY	\$343	0%	0%	0%	0%
CARDIOLOGY	\$6,498	0%	0%	0%	0%
CHIROPRACTOR	\$789	0%	0%	0%	0%
CLINICAL PSYCHOLOGIST	\$720	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	\$558	0%	0%	0%	0%
COLON AND RECTAL SURGERY	\$161	-1%	0%	0%	-1%
CRITICAL CARE	\$296	0%	0%	0%	0%
DERMATOLOGY	\$3,217	0%	0%	0%	1%
DIAGNOSTIC TESTING FACILITY	\$725	0%	0%	0%	0%
EMERGENCY MEDICINE	\$3,120	0%	0%	0%	0%
ENDOCRINOLOGY	\$454	0%	0%	0%	0%
FAMILY PRACTICE	\$6,089	0%	0%	0%	0%
GASTROENTEROLOGY	\$1,843	-2%	-1%	-1%	-4%
GENERAL PRACTICE	\$478	0%	0%	0%	0%
GENERAL SURGERY	\$2,210	0%	0%	0%	0%
GERIATRICS	\$216	0%	0%	0%	0%
HAND SURGERY	\$169	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	\$1,788	0%	0%	0%	0%
INDEPENDENT LABORATORY	\$834	1%	7%	0%	9%
INFECTIOUS DISEASE	\$660	0%	0%	0%	0%
INTERNAL MEDICINE	\$11,058	0%	0%	0%	0%
INTERVENTIONAL PAIN MGMT	\$720	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	\$298	0%	1%	0%	1%
MULTISPECIALTY CLINIC/OTHER PHYS	\$96	0%	0%	0%	0%
NEPHROLOGY	\$2,199	0%	0%	0%	0%
NEUROLOGY	\$1,524	0%	-1%	0%	-1%
NEUROSURGERY	\$776	0%	0%	-1%	-1%
NUCLEAR MEDICINE	\$46	0%	0%	0%	-1%
NURSE ANES / ANES ASST	\$1,187	0%	2%	-2%	0%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
NURSE PRACTITIONER	\$2,551	0%	0%	0%	0%
OBSTETRICS/GYNECOLOGY	\$669	0%	0%	0%	0%
OPHTHALMOLOGY	\$5,506	0%	0%	0%	-1%
OPTOMETRY	\$1,178	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	\$47	0%	0%	0%	0%
ORTHOPEDIC SURGERY	\$3,672	0%	0%	0%	0%
OTHER	\$25	0%	0%	0%	0%
OTOLARNGOLOGY	\$1,197	0%	0%	0%	0%
PATHOLOGY	\$1,330	4%	4%	0%	8%
PEDIATRICS	\$59	0%	0%	0%	0%
PHYSICAL MEDICINE	\$1,035	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	\$3,102	0%	0%	0%	0%
PHYSICIAN ASSISTANT	\$1,728	0%	0%	0%	0%
PLASTIC SURGERY	\$376	0%	0%	0%	1%
PODIATRY	\$1,999	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	\$106	0%	1%	0%	1%
PSYCHIATRY	\$1,317	0%	0%	0%	0%
PULMONARY DISEASE	\$1,780	0%	0%	0%	0%
RADIATION ONCOLOGY	\$1,776	0%	-2%	0%	-2%
RADIATION THERAPY CENTERS	\$52	0%	-2%	0%	-1%
RADIOLOGY	\$4,494	0%	0%	0%	0%
RHEUMATOLOGY	\$536	0%	0%	0%	0%
THORACIC SURGERY	\$350	0%	0%	0%	0%
UROLOGY	\$1,796	0%	0%	0%	0%
VASCULAR SURGERY	\$1,019	0%	-1%	0%	-1%

** 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 final rule with comment period, 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 gastroenterology and radiation oncology, 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 proposed 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 62 displays the estimated CY 2016 combined impact on total allowed charges by specialty of all the RVU changes. Table 63 (Impact on CY 2016 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the 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 website at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/>.

TABLE 63: Impact 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	\$25.44	1%	\$45.28	\$45.50	0%
17000		Destruct premalg lesion	\$53.90	\$54.46	1%	\$67.20	\$67.71	1%
27130		Total hip arthroplasty	\$1,407.87	\$1,404.45	0%	NA	NA	NA
27244		Treat thigh fracture	\$1,277.80	\$1,279.41	0%	NA	NA	NA
27447		Total knee arthroplasty	\$1,407.52	\$1,404.45	0%	NA	NA	NA
33533		Cabg arterial single	\$1,952.63	\$1,952.62	0%	NA	NA	NA
35301		Rechanneling of artery	\$1,203.41	\$1,198.80	0%	NA	NA	NA
43239		Egd biopsy single/multiple	\$154.15	\$151.19	-2%	\$412.52	\$405.21	-2%
66821		After cataract laser surgery	\$316.21	\$316.00	0%	\$334.90	\$334.27	0%
66984		Cataract surg w/iol 1 stage	\$650.40	\$642.39	-1%	NA	NA	NA
67210		Treatment of retinal lesion	\$508.82	\$509.47	0%	\$526.79	\$527.03	0%
71010		Chest x-ray 1 view frontal	NA	NA	NA	\$22.64	\$22.57	0%
71010	26	Chest x-ray 1 view frontal	\$9.34	\$9.32	0%	\$9.34	\$9.32	0%
77056		Mammogram both breasts	NA	NA	NA	\$116.42	\$116.44	0%
77056	26	Mammogram both breasts	\$44.56	\$44.43	0%	\$44.56	\$44.43	0%
77057		Mammogram screening	NA	NA	NA	\$83.01	\$83.12	0%
77057	26	Mammogram screening	\$35.93	\$35.83	0%	\$35.93	\$35.83	0%
77427		Radiation tx management x5	\$187.57	\$187.74	0%	\$187.57	\$187.74	0%
88305	26	Tissue exam by pathologist	\$39.17	\$39.77	2%	\$39.17	\$39.77	2%
90935		Hemodialysis one evaluation	\$73.66	\$73.09	-1%	NA	NA	NA
92012		Eye exam establish patient	\$53.18	\$53.38	0%	\$86.24	\$85.99	0%
92014		Eye exam&tx estab pt 1/>vst	\$80.85	\$80.97	0%	\$124.69	\$124.68	0%
93000		Electrocardiogram complete	NA	NA	NA	\$17.25	\$17.20	0%
93010		Electrocardiogram report	\$8.62	\$8.60	0%	\$8.62	\$8.60	0%
93015		Cardiovascular stress test	NA	NA	NA	\$77.26	\$75.60	-2%
93307	26	Tte w/o doppler complete	\$45.99	\$45.86	0%	\$45.99	\$45.86	0%
93458	26	L hrt artery/ventricle angio	\$323.76	\$323.88	0%	\$323.76	\$323.88	0%

CPT/ HCPCS ¹	MOD	Short Descriptor	Facility			Non Facility		
			CY 2015 ²	CY 2016 ³	% Change	CY 2015 ²	CY 2016 ³	% Change
98941		Chiropract manj 3-4 regions	\$35.21	\$34.75	-1%	\$41.32	\$41.20	0%
99203		Office/outpatient visit new	\$77.98	\$77.75	0%	\$109.60	\$109.28	0%
99213		Office/outpatient visit est	\$51.38	\$51.59	0%	\$73.30	\$73.45	0%
99214		Office/outpatient visit est	\$79.41	\$79.18	0%	\$108.88	\$108.20	-1%
99222		Initial hospital care	\$139.06	\$138.30	-1%	NA	NA	NA
99223		Initial hospital care	\$205.90	\$204.22	-1%	NA	NA	NA
99231		Subsequent hospital care	\$39.53	\$39.77	1%	NA	NA	NA
99232		Subsequent hospital care	\$73.30	\$72.73	-1%	NA	NA	NA
99233		Subsequent hospital care	\$105.64	\$104.98	-1%	NA	NA	NA
99236		Observ/hosp same date	\$220.99	\$219.63	-1%	NA	NA	NA
99239		Hospital discharge day	\$108.88	\$108.20	-1%	NA	NA	NA
99283		Emergency dept visit	\$62.88	\$62.70	0%	NA	NA	NA
99284		Emergency dept visit	\$119.66	\$118.95	-1%	NA	NA	NA
99291		Critical care first hour	\$227.46	\$226.07	-1%	\$279.20	\$277.67	-1%
99292		Critical care addl 30 min	\$113.55	\$113.22	0%	\$124.33	\$123.96	0%
99348		Home visit est patient	NA	NA	NA	\$84.80	\$85.27	1%
99350		Home visit est patient	NA	NA	NA	\$178.95	\$179.14	0%
G0008		Immunization admin	NA	NA	NA	\$25.51	\$25.44	0%

¹CPT codes and descriptions are copyright 2016 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

²Payments based on the July- December 2015 conversion factor of 35.9335.

³Payments based on the 2016 conversion factor of \$35.8279.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.I. of this final rule with comment period, we proposed to add several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions.

E. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule

As discussed in section III.A.2 of this final rule with comment period, 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 finalizing our proposal to correct the dates in the Code of Federal Regulations (CFR) at §414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

As discussed in section III.A.3 of this final rule with comment period, we are finalizing our proposal to continue, for CY 2016 and subsequent CYs, 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). As discussed previously, the continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs means 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 will 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 will 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 final rule with comment period, the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs will continue to affect whether certain areas are designated as urban or rural, and whether or not transports will be eligible for rural adjustments under the ambulance fee schedule statute and regulations. Descriptions of our final policies and accompanying rationale, as well as our responses to comments, are set forth in more detail in section III.A.3. of the final rule with comment period. We estimate that our continued implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs will 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 will result in a minimal fiscal impact on ambulance providers and suppliers as compared to CY 2015, because we will 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 continued implementation of the revised OMB delineations and updated RUCA codes will 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 final rule with comment period describing certain impacts associated with implementation of these geographic delineations. As further discussed in section III.A.3. of this

final rule with comment period, Table 23 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 August 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, as discussed in section III.A.4. of this final rule with comment period, we are revising §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 revising the definition of Basic Life Support (BLS) in §414.605 to include the revised staffing requirements discussed above for §410.41(b). Since we expect ambulance providers and suppliers are already in compliance with their state and local laws, we expect that these revisions will have a minimal impact on ambulance providers and suppliers. Similarly, we do not expect any significant impact on the Medicare program.

Furthermore, we are revising §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 more clearly states our current policy. Also, for the reasons discussed in section III.A.4. of this final rule with comment period, we are deleting the last sentence of our definition of BLS in §414.605. Because these revisions do not change our current policies, we expect they will 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 final rule with comment period, we proposed 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 proposed 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 3.4 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 \$60 million in Part B payments. We estimate that the 10-year cost impact of CCM payment in RHCs and FQHCs would be \$190 million, of which \$30 million is the premium offset and \$160 million 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 0.034 (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). This estimate was then phased in based on the current utilization under the physician fee schedule.

Table 64 provides the yearly estimates (figures are in millions):

TABLE 64: 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	-	\$10	\$10	\$20	\$20	\$20	\$20	\$30	\$30	\$30	\$60	\$190
Premium Offset	-	-	-	-	-	-	-	\$ (10)	\$ (10)	\$ (10)	\$ -	\$(30)
Total Part B	-	\$10	\$10	\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$60	\$160

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

As discussed in section III.C. of this final rule with comment period, we proposed to require HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016 to allow the MACs additional time to implement the necessary claims processing systems changes completely. There will be no cost impact on the Medicare program since this requirement does not change the payment methodology for RHC services. This requirement 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 final rule with comment period, we proposed 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 proposed 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 did not propose 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 final rule with comment period, we discuss the payment of biosimilar biological products under section 1847A of the Act and the proposal 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 final rule, we had not yet received ASP data for any biosimilar biological products that had been approved under the FDA's biosimilar approval pathway. Information from pharmaceutical pricing compendia for one approved biosimilar product has become available since the proposed rule was written, and a comparison of compendia prices for the biosimilar product and its reference product agrees with our expectation that the Medicare program will see some degree of savings from biosimilars. At this time, it is still not clear how many biosimilar products will be approved, when approval and marketing of various products will occur, or what the market penetration of biosimilars in Medicare will be. It is also not clear what the cost differences

between the each of the biosimilars will be or what the price differences between the biosimilars and the reference products will be as the market develops. 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

The Appropriate Use Criteria (AUC) development process requirements, as well as an application process that organizations must comply with to become qualified provider-led entities (PLEs) do not impact CY 2016 physician payments under the PFS.

7. Physician Compare

We do not estimate any impact as a result of the final policies for the Physician Compare website.

8. 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.”¹² 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

¹² 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.

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 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.¹³ 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.

¹³ Id. at XV.

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 \text{ hr} \times \$26.68/\text{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 2012.¹⁴ 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

¹⁴ Id. at xvi. *See* Figure 4.

individual eligible professionals and group practices only 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 x 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 x \$83.96/hour) to \$151.13 (108 minutes or 1.8 hours x \$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 2012.¹⁵ 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

¹⁵ Id. at xvi. See Figure 4.

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.¹⁶ 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, 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

¹⁶ 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>.

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 x 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 final rule with comment period, we proposed 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.¹⁷ 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

¹⁷ Id. at XV.

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 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 final rule with comment period, we are finalizing a policy that group practices of 100 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 100 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.¹⁸ In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).¹⁹ These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).²⁰ 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 Shared Saving Program 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 Medicare Shared Savings Program ACOs. 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 ACOs, and Medicare Shared Savings Program ACOs). However, not all group practices use the

¹⁸ Id. at xv.

¹⁹ Id. at xvi.

²⁰ Id. at 18.

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 x 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.

9. EHR Incentive Program

The changes to the EHR Incentive Program in section III.J of this final rule with comment period would not impact the current burden estimate for the EHR Incentive Program.

10. Comprehensive Primary Care (CPC) Initiative and Medicare EHR Incentive Program

Aligned Reporting

The establishment of an aligned reporting option between CPC and the Medicare EHR Incentive Program does not impact the CY 2016 payments under PFS.

11. 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.

12. 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 finalizing certain conforming changes to align with PQRS, including a change to the quality measure set. We also are finalizing 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 finalizing updates to the assignment methodology to include claims submitted by electing teaching amendment hospitals and to exclude certain claims for services performed in SNFs. Since the finalized 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.

13. 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 as well as those groups of physicians and physicians that fail to avoid the PQRS payment adjustment as a group or as individuals.

Unless specified, the changes to the VM in section III.M of this final rule with comment period 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 EPs 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 65.

TABLE 65: 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 Category 1 groups' downward payment adjustments under quality-tiering, in Table 65 with the Category 2 groups' -2.0 percent automatic downward payment adjustments. 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.

On September 8, 2015, we made the 2014 Annual QRURs available to all groups and solo practitioners based on their performance in CY 2014. We also completed a preliminary analysis (prior to accounting for the informal review process) 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 and present a summary of the findings below. Please note that the impact of the policies for the CY 2018 VM finalized in this final rule with comment period will be discussed in the PFS rule for CY 2018.

Based on the methodology codified in §414.1210(c), there are 13,785 groups of 10 or more EPs (as identified by their Taxpayer Identification Numbers (TINs)) whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2016 payment adjustment period. Of these 13,785 groups subject to the CY 2016 VM, preliminary results show that 8,357 groups met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2016 VM. Of the 8,357 groups in Category 1, there

are 7,639 groups of physicians with between 10 and 99 EPs and 718 groups of physicians with 100 or more EPs. As noted in this section, these are preliminary numbers and may be subject to change as a result of the informal review process. We release the actual number of upward and downward adjustments, along with the adjustment factor after the conclusion of the informal review process.

Of the 7,639 groups of physicians with between 10 and 99 EPs, preliminary results found that 110 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x; 42 of those groups qualify for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; and 7,529 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. Of the 718 groups of physicians with 100 or more EPs, our preliminary results showed that 9 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x, with 4 of those groups qualifying for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; 54 groups are in tiers that will result in a downward adjustment of between -1.0 and -2.0 percent; and 655 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. We will announce the final quality-tiering results along with the upward payment adjustment factor (x) in the late 2015 on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html>. Tables 66 shows the preliminary distribution of the groups with between 10 and 99 EPs in Category 1 into the various quality and cost tiers. Tables 67 shows the preliminary distribution of the groups with 100 or more EPs in Category 1 into the various quality and cost tiers.

TABLE 66: Preliminary Distribution Using 2014 Data of Quality and Cost Tiers for Groups with between 10 to 99 EPs (7,639 Groups)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	0.0% (6)	+ [1.0/2.0]x (50)	+ [2.0/3.0]x (1)
Average Cost	0.0% (589)	0.0% (6,700)	+ [1.0/2.0]x (59)
High Cost	0.0% (32)	0.0% (201)	0.0% (1)

TABLE 67: Preliminary Distribution Using 2014 Data of Quality and Cost Tiers for Groups with 100 or More EPs (718 Groups)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	0.0% (0)	+ [1.0/2.0]x (6)	+ [2.0/3.0]x (0)
Average Cost	-1.0% (31)	0.0% (655)	+ [1.0/2.0]x (3)
High Cost	-2.0% (0)	-1.0% (23)	0.0% (0)

Of the 13,785 groups subject to the CY 2016 VM, preliminary results found that 5,428 groups met the criteria for inclusion in Category 2. As noted above, Category 2 includes groups that do not fall within Category 1. Groups in Category 2 will be subject to a -2.0 percent payment adjustment under the VM during the CY 2016 payment adjustment period.

In CY 2016, only the physicians in groups with 10 or more EPs will be subject to the VM.

We note that in the 2014 QRUR Experience Report, which we intend to release in early 2016, we will provide a detailed analysis of the impact of the 2016 VM policies on groups of 10 or more EPs subject to the VM in CY 2016, including findings based on the data contained in the 2014 QRURs for all groups and solo practitioners.

14. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.N. of this final rule with comment period. We did not receive any comments on the physician self-referral updates regulatory impact section of the 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 the physician self-referral update provisions in this final rule with comment period will reduce burden by clarifying previous guidance. We believe these provisions will allow parties to determine with greater certainty whether their financial relationships comply with an exception.

We are also issuing new exceptions and a new definition that will accommodate legitimate financial arrangements while continuing to protect against program and patient abuse:

- In section III.N.2.a of this final rule with comment period, we discuss a limited new exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to physicians to assist with the compensation of a nonphysician practitioner. This new exception would promote access to primary medical and mental health care services, a goal of the Secretary and the Affordable Care Act.

- In section III.N.2.b of this final rule with comment period, we describe the new definition of the geographic area served by an FQHC or RHC we are adding to physician recruitment exception. This new definition will provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception.

- In section III.N.7 of this final rule with comment period, we discuss a new exception that will protect timeshare arrangements that meet certain criteria. This new exception will 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 will reduce the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

- In section III.N.9.b of this final rule with comment period, we discuss the requirement 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 may have revised bona fide investment levels that may exceed the baseline bona fide investment levels calculated under our previous guidance. As discussed in section III.N.9.b, while we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

15. Opt out Change

We revised 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 final rule with comment period 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 final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned 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 63, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was \$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 final rule with comment period, using the CY 2016 CF, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 63, is \$109.28, which means that, in CY 2016, the proposed beneficiary coinsurance for this service would be \$21.86.

H. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 66 (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 66: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2016 Annualized Monetized Transfers	Estimated increase in expenditures of \$0.0 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2016 Annualized Monetized Transfers	Estimated increase in payment of \$0.0 billion.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 67: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2016 Annualized Monetized Transfers of beneficiary cost coinsurance.	\$0.0 billion
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 Subjects42 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, 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 amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 405.400 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 (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 Cancellation of opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written notice to each Medicare Administrative Contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

(b) * * *

(2) Notify all Medicare Administrative 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 paragraphs (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. Removing in paragraph (b)(2) 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 billing as if it were 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) Eighty (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) Eighty (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 grandfathered tribal FQHCs that are authorized to bill at this rate.

* * * * *

(g) * * *

(3) HCPCS coding. FQHCs and RHCs 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), (2), and (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. This rates is 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, 1395rr, and 1395ddd).

19. Section 410.15, paragraph (a), is amended by—

a. In the definition of “First annual wellness visit providing personalized prevention plan services”, revising paragraph (x) and adding paragraph (xi).

b. In the definition of “Subsequent annual wellness visit providing personalized prevention plan services”, revising paragraph (viii) and adding paragraph (ix).

The revisions and additions read as follows:

§410.15 Annual wellness visits providing Personalized Prevention Plan Services:

Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services * * *

(x) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(xi) Any other element determined appropriate through the national coverage determination process.

* * * * *

Subsequent wellness visit providing personalized prevention plan services * * *

(viii) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(ix) Any other element determined appropriate through the national coverage determination process.

* * * * *

20. 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, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Services and supplies furnished incident to transitional care management and chronic care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff. The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services

* * * * *

21. 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.

* * * * *

22. 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.

* * * * *

23. 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

24. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn).

25. Section 411.351 is amended by—

a. In the definition of “Entity”, 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. In the definition of “Parenteral and enteral nutrients, equipment, and supplies”, revising paragraphs (1) and (2).

d. Revising the definition of “Physician in the group practice”.

e. In the definition of “Remuneration”, 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.

* * * * *

“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.

* * * * *

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 website 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.

* * * * *

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.

* * * * *

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.

* * * * *

26. 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), (b)(1), (d)(1)(i), (e)(1)(i), (e)(4)(i), (l)(1), (p)(2), (q) (incorporating the requirement contained in §1001.952(f)(4) of this title), (r)(2)(ii), (t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in §411.357(e)(1)(i)), (v)(7)(i), (w)(7)(i), (x)(1)(i), or (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.

* * * * *

27. 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 paragraph (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.

28. 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 (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.

* * * * *

29. Section 411.357 is amended by—

a. Revising paragraphs (a) introductory text, (a)(1) through (4), (a)(5) introductory text,

(a)(6) and (7), (b)(1) through (3), (b)(4) introductory text, (b)(5) and (6), (c)(3), (d)(1)(iii), (iv) and (vii), (e)(1)(iii) and (iv), (e)(4)(i) and (iv), (e)(6), (f)(2), (k)(2), (l) introductory text, (l)(1) and (2), (m)(1) through (3), (m)(5), (p)(1)(ii)(A), (p)(2), (r)(2)(iv) and (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 duration 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 duration 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 duration 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 or noncontiguous 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. 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 website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

* * * * *

(1) 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 website 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 website or in hospital advertising, meets the “on campus” requirement of this paragraph (m).

* * * * *

(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 website 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 compensate a nonphysician practitioner. (1) Remuneration provided by a hospital to a physician to compensate 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 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); 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 compensation, 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 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(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)(A) The nonphysician practitioner has a compensation arrangement with the physician or the physician organization in whose shoes the physician stands under §411.354(c); and

(B) Substantially all of the services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(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, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined in §410.71(d) of this subchapter.

(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) For purposes of paragraph (x)(1) of this section, a “compensation arrangement” between a physician (or the physician organization in whose shoes the physician stands under §411.354(c) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner’s ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(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 under an arrangement for the use of 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 arrangement is between a physician (or the physician organization in whose shoes the physician stands under §411.354(c) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients;
and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building 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 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 referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(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 while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(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.

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

30. 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.

* * * * *

31. Section 411.362 is amended by—

a. In paragraph (a):

i. Effective January 1, 2017, adding the definition of “Ownership or investment interest”

in alphabetical order; and

ii. Adding the definition of “Public advertising for the hospital” in alphabetical order.

b. Revising paragraphs (b)(3)(ii)(C), (c)(2)(iv) and (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 website 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 website for the hospital does not include, by way of example: social media websites; 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 website State average bed capacities and the national average bed capacity. For purposes of this paragraph (c)(2)(iv), “sufficient number” means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(iv) 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 website State average bed occupancy rates. For purposes of this paragraph (c)(2)(v), “sufficient

number” means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(v) 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 website 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.

* * * * *

32. 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 website.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

33. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

34. Section 414.90 is amended by—

- a. Adding paragraphs (j)(8) and (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 paragraph (k)(5).

The additions and revisions read as follows:

§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 must 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 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, 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 2 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, 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.

(B) [Reserved]

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO must administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(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) of this section 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]

* * * * *

35. 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. An AUC set is a collection of individual appropriate use criteria. An individual criterion 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 conditions, diseases or symptom complexes and associated advanced diagnostic imaging services 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 (PLE) means a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care.

Specified applicable appropriate use criteria means any individual appropriate use criterion or AUC set developed, modified or endorsed by a qualified PLE.

(c) Qualified provider-led entity. To be qualified by CMS, a PLE must adhere to the evidence-based processes described in paragraph (c)(1) of this section when developing or modifying AUC. A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other qualified PLEs.

(1) Requirements for qualified PLEs developing or modifying AUC. A PLE must perform all of the following when developing or modifying AUC:

(i) Utilize an evidentiary review process when developing or modifying AUC 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) Utilize at least one multidisciplinary team with autonomous governance, decision-making and accountability for developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner as described in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act, at least one expert in statistical analysis and at least one expert in clinical trial design. A given team member may be the team's expert in more than one domain.

(iii) Utilize a publicly transparent process for identifying potential conflicts of interest and for resolving conflicts of interest of members on the multidisciplinary team, the PLE and any other party participating in AUC development or modification, to include recusal or exclusion of individuals as appropriate. The PLE must document the following information and make it available in timely fashion to a public request, for a period of not less than 5 years after the most recent published update of the relevant AUC:

(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 including the PLE and any other party participating in AUC development or modification that may financially benefit from the AUC. These financial

relationships may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements.

(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 including the PLE or any other party participating in AUC development or modification that may financially benefit from the AUC.

(iv) Publish each individual criterion on the PLE's website and include an identifying title, authors (at a minimum, all members of the multidisciplinary AUC development team must be listed as authors), and key references used to establish the evidence.

(v) Identify each appropriate use criterion or AUC subset that are relevant to a priority clinical area with a statement on the PLE's website. To be identified as being relevant to a priority clinical area, the criterion or AUC subset must reasonably address the entire clinical scope of the corresponding priority clinical area.

(vi) Identify key points in an individual criterion as evidence-based or consensus-based, and grade such key points in terms of strength of evidence using a formal, published and widely recognized methodology.

(vii) Utilize a transparent process for the timely and continual updating of each criterion. Each criterion must be reviewed and, when appropriate, updated at least annually.

(viii) Publicly post the process for developing or modifying the AUC on the PLE's website.

(ix) Disclose parties external to the PLE when such parties have involvement in the AUC development process.

(2) Process to identify qualifying PLEs. PLEs must meet all of the following criteria:

(i) PLEs must submit an application to CMS for review 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 PLEs that meet the definition of PLE in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved qualified PLEs in each year will be included on the list of qualified PLEs posted to the CMS website by June 30 of that year; and

(v) Approved PLEs are qualified for a period of 5 years.

(vi) Qualified PLEs are required to re-apply. The application must be received by CMS by January 1 of the 5th year after the PLE's most recent approval date.

(d) Endorsement. Qualified PLEs may endorse the AUC set or individual criteria of other qualified PLEs, under agreement by the respective parties, in order to enhance an AUC set.

(e) Identifying priority clinical areas. (1) CMS identifies priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, the volume and variability of use of particular imaging services, and strength of evidence supporting particular 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).

(f) Identification of non-evidence-based AUC or other non-adherence to requirements for qualified PLEs. (1) CMS will accept public comment to facilitate identification of AUC sets, subsets or individual criterion that are not evidence-based, giving priority to AUC associated with priority clinical areas and to AUC that conflict with one another. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

(3) If a qualified PLE is found non-adherent to the requirements in paragraph (c) of this section, CMS may terminate its qualified status or may consider this information during re-qualification.

36. 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]

37. 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”.

38. 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).

39. 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.

* * * * *

40. Section 414.1210 is amended by—

- a. Revising paragraph (a)(4), (b)(2)(i)(B), (C), and (D), (b)(3), (b)(4), and (c).
- b. Adding paragraphs (b)(2)(i)(E) and (F).

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 of physicians with 10 or more eligible professionals and equal to -2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of $+3x$ (rather than $+2x$) if the group has 10 or more eligible professionals or $+2x$ (rather than $+1x$) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275 for the payment adjustment period, except that if the ACO 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 of physicians has 10 or more

eligible professionals, +2x (rather than +1x) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2x (rather than +1x) for a solo practitioner who is a nonphysician eligible professional or if the group consists 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 paragraph (b)(2) of this section, 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) Application of the value-based payment modifier to participants in the Pioneer ACO Model and the Comprehensive Primary Care Initiative. (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 paragraph (a) of this section, 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.

41. 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.

42. Section 414.1230 is amended by revising paragraph (c) to read as follows:

§414.1230 Additional measures for groups and solo practitioners.

* * * * *

(c) Rates of an all-cause hospital readmissions measure, except for groups with between two to nine eligible professionals and solo practitioners starting with the CY 2017 payment adjustment period.

43. Section 414.1235 is amended by adding paragraphs (c)(4) and (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.

44. 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, QCDR, 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, eQMs reported via EHRs are excluded from the overall benchmark for quality of care measures and separate eQm benchmarks will be developed. The eQm 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.

* * * * *

45. 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.

46. Section 414.1265 is amended by adding paragraph (a)(2) and revising paragraphs (a)(1) and (b) to read as follows:

§414.1265 Reliability of measures.

* * * * *

(a) * * *

(1) Starting with the CY 2017 payment adjustment period, the exception to this paragraph (a) is the all-cause hospital readmissions measure described at §414.1230(c). In a performance period, if a group has fewer than 200 cases for this all-cause hospital readmissions measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(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 125 episodes 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.

47. Section 414.1270 is amended by removing paragraphs (b)(5) and (c)(5), revising paragraph (c)(1)(i), and adding paragraph (d) to read as follows:

§414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(c) * * *

(1) * * *

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; and

* * * * *

(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).

48. 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 of Physicians 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 of Physicians 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

49. 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).

50. Section 425.20 is amended in the definition of “Primary care services” by revising paragraph (2) introductory text and adding paragraphs (2)(v) and (4) to 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.

* * * * *

51. 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 subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

* * * * *

52. Section 425.402 is 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.

53. Section 425.502 is amended by –

a. Adding paragraph (a)(5)

b. In paragraph (d)(2)(ii), removing the reference “§425.216(c)” and adding in its place the reference “§425.216”.

The addition reads 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]

54. 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

55. 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).

56. In §495.4 the definition of “Certified electronic health record technology (CEHRT)” is amended by revising paragraphs (1)(ii)(B)(3) and (2)(ii)(B) to read as follows:

§495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(1) * * *

(ii) * * *

(B) * * *

(3) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (3); or 45 CFR 170.315(c)(3)(i) and (ii); and can be electronically accepted by CMS if the provider is submitting electronically.

* * * * *

(2) * * *

(ii) * * *

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii), and can be electronically accepted by CMS.

* * * * *

Dated: October 27, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 28, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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