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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 412, 413, 414, 425, 489, 495, and 498

[CMS-1612-FC]

RIN 0938-AS12

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

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. See the Table of Contents for a listing of the specific issues addressed in this rule.

DATES: Effective date: The provisions of this final rule are effective on January 1, 2015, with the exception of amendments to parts 412, 413, and 495 which are effective **October 31, 2014**.

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 30, 2014.

Compliance date: The compliance date for new data collection requirements in §403.904(c)(8) is January 1, 2016.

ADDRESSES: In commenting, please refer to file code CMS-1612-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-1612-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-1612-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 any physician payment issues not identified below.

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

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology, impacts, the sustainable growth rate, conscious sedation, or conversion factors.

Kathy Kersell, (410) 786–2033, for issues related to direct practice expense inputs.

Jessica Bruton, (410) 786-5991, for issues related to potentially misvalued services or work RVUs.

Craig Dobyski, (410) 786–4584, for issues related to geographic practice cost indices or malpractice RVUs.

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

Pam West, (410) 786-2302, for issues related to conditions for therapists in private practice or therapy caps.

Ann Marshall, (410) 786-3059, for issues related to chronic care management.

Marianne Myers, (410) 786-5962, for issues related to ambulance extender provisions.

Amy Gruber, (410) 786-1542, for issues related to changes in geographic area designations for ambulance payment.

Anne Tayloe-Hauswald, (410) 786–4546, for issues related to clinical lab fee schedule.

Corinne Axelrod, (410) 786–5620, for issues related to Rural Health Clinics or Federally Qualified Health Centers.

Renee Mentnech, (410) 786-6692, for issues related to access to identifiable data for the Centers for Medicare & Medicaid models.

Marie Casey, (410) 786-7861 or Karen Reinhardt (410) 786-0189 for issues related to local coverage determination process for clinical diagnostic laboratory tests.

Frederick Grabau, (410) 786-0206, for issues related to private contracting/opt-out.

David Walczak, (410) 786-4475, for issues related to payment policy for substitute physician billing arrangements (locum tenens).

Melissa Heesters, (410) 786-0618, for issues related to reports of payments or other transfers of value to covered recipients.

Alesia Hovatter, (410) 786-6861, for issues related to physician compare.

Christine Estella, (410) 786-0485, for issues related to the physician quality reporting system.

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

Patrice Holtz, (410)786–5663, for issues related to comprehensive primary care initiative.

Terri Postma, (410) 786-4169, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, for issues related to value-based modifier and improvements to physician feedback.

Elizabeth Holland, (410) 786-1309, Medicare EHR Incentive Program (Medicare payment adjustments and hardship exceptions).

Elisabeth Myers (CMS), (410) 786-4751, Medicare EHR Incentive Program (Medicare payment adjustments and hardship exceptions).

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.

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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)
BBA	Balanced Budget Act of 1997 (Pub. L. 105-33)
BBRA	[Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)
CAD	Coronary artery disease
CAH	Critical access hospital
CBSA	Core-Based Statistical Area
CCM	Chronic care management
CEHRT	Certified EHR technology
CF	Conversion factor
CG-CAHPS	Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS	Clinical Laboratory Fee Schedule
CNM	Certified nurse-midwife
CP	Clinical psychologist
CPC	Comprehensive Primary Care
CPEP	Clinical Practice Expert Panel
CPT	[Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2014 American Medical Association. All rights reserved.*)
CQM	Clinical quality measure
CSW	Clinical social worker
CT	Computed tomography

CY	Calendar year
DFAR	Defense Federal Acquisition Regulations
DHS	Designated health services
DM	Diabetes mellitus
DSMT	Diabetes self-management training
eCQM	Electronic clinical quality measures
EHR	Electronic health record
E/M	Evaluation and management
EP	Eligible professional
eRx	Electronic prescribing
ESRD	End-stage renal disease
FAR	Federal Acquisition Regulations
FFS	Fee-for-service
FQHC	Federally qualified health center
FR	**Federal Register**
GAF	Geographic adjustment factor
GAO	Government Accountability Office
GPCI	Geographic practice cost index
GPO	Group purchasing organization
GPRO	Group practice reporting option
GTR	Genetic Testing Registry
HCPCS	Healthcare Common Procedure Coding System
HHS	[Department of] Health and Human Services
HOPD	Hospital outpatient department
HPSA	Health professional shortage area

IDTF	Independent diagnostic testing facility
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
ISO	Insurance service office
IWPUT	Intensity of work per unit of time
LCD	Local coverage determination
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAP	Measure Applications Partnership
MAPCP	Multi-payer Advanced Primary Care Practice
MAV	Measure application validity [process]
MCP	Monthly capitation payment
MedPAC	Medicare Payment Advisory Commission
MEI	Medicare Economic Index
MFP	Multi-Factor Productivity
MIPPA	Medicare Improvements for Patients and Providers Act (Pub. L. 110-275)
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003)
MP	Malpractice
MPPR	Multiple procedure payment reduction
MRA	Magnetic resonance angiography
MRI	Magnetic resonance imaging
MSA	Metropolitan Statistical Areas
MSPB	Medicare Spending per Beneficiary
MSSP	Medicare Shared Savings Program

MU	Meaningful use
NCD	National coverage determination
NCQDIS	National Coalition of Quality Diagnostic Imaging Services
NP	Nurse practitioner
NPI	National Provider Identifier
NPP	Nonphysician practitioner
NQS	National Quality Strategy
OACT	CMS's Office of the Actuary
OBRA '89	Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239)
OBRA '90	Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101- 508)
OES	Occupational Employment Statistics
OMB	Office of Management and Budget
OPPS	Outpatient prospective payment system
OT	Occupational therapy
PA	Physician assistant
PAMA	Protecting Access to Medicare Act of 2014 (Pub. L. 113-93)
PC	Professional component
PCIP	Primary Care Incentive Payment
PE	Practice expense
PE/HR	Practice expense per hour
PEAC	Practice Expense Advisory Committee
PECOS	Provider Enrollment, Chain, and Ownership System
PFS	Physician Fee Schedule
PLI	Professional Liability Insurance
PMA	Premarket approval

PQRS	Physician Quality Reporting System
PPIS	Physician Practice Expense Information Survey
PT	Physical therapy
PY	Performance year
QCDR	Qualified clinical data registry
QRUR	Quality and Resources Use Report
RBRVS	Resource-based relative value scale
RFA	Regulatory Flexibility Act
RHC	Rural health clinic
RIA	Regulatory impact analysis
RUC	American Medical Association/Specialty Society Relative (Value) Update Committee
RUCA	Rural Urban Commuting Area
RVU	Relative value unit
SBA	Small Business Administration
SGR	Sustainable growth rate
SIM	State Innovation Model
SLP	Speech-language pathology
SMS	Socioeconomic Monitoring System
SNF	Skilled nursing facility
TAP	Technical Advisory Panel
TC	Technical component
TIN	Tax identification number
UAF	Update adjustment factor
UPIN	Unique Physician Identification Number

USPSTF United States Preventive Services Task Force

VBP Value-based purchasing

VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS 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 2015 PFS final rule with comment period, refer to item CMS–1612–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.henson1@cms.hhs.gov.

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 2013 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 polices 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 2015.

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, 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 2015 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:

- Misvalued PFS Codes.
- Telehealth Services.
- Chronic Care Management Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Updating the Ambulance Fee Schedule regulations.
- Changes in Geographic Area Delineations for Ambulance Payment.
- Updating the-

++ 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 proposed changes would affect the specialty distribution of Medicare expenditures. When considering the combined impact of work, PE, and MP RVU changes, the projected payment impacts are small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this 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 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.C. 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.

With regard to MP RVUs, we completed five-year reviews of MP that were effective in CY 2005 and CY 2010. This final rule with comment period establishes a five-year review for CY 2015.

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 caused expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures did not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each physicians' 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 physician work, PE, and MP in an area compared to the national average costs for each component. (See section II.D. of this final rule with comment period for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The CF for a given year is calculated using (a) the productivity-adjusted increase in the Medicare Economic Index (MEI) and (b) the Update Adjustment Factor (UAF), which is calculated by taking into account the Medicare Sustainable Growth Rate (SGR), an annual growth rate intended to control growth in aggregate Medicare expenditures for physicians' services, and the allowed and actual expenditures for physicians' services. The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

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

3. Separate Fee Schedule Methodology for Anesthesia Services

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

4. Most Recent Changes to the Fee Schedule

The CY 2014 PFS final rule with comment period (78 FR 74230) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2013 interim final RVUs and established interim final RVUs for new and revised codes for CY 2014 to ensure that our payment system is updated to reflect changes in medical practice, coding changes, and the relative values of services. It also implemented section 635 of the American Taxpayer Relief Act of 2012 (Pub. L. 112-240, enacted on January 2, 2013) (ATRA), which revised the equipment utilization rate assumption for advanced imaging services furnished on or after January 1, 2014.

Also, in the CY 2014 PFS final rule with comment period, we announced the following for CY 2014: the total PFS update of -20.1 percent; the initial estimate for the SGR of -16.7 percent; and a CF of $27.2006. These figures were calculated based on the statutory provisions in effect on November 27, 2013, when the CY 2014 PFS final rule with comment period was issued.

The Pathway for SGR Reform Act of 2013 (Pub. L. 113-67, enacted on December 26, 2013) established a 0.5 percent update to the PFS CF through March 31, 2014 and the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93, enacted on April 1, 2014) (PAMA) extended this 0.5 percent update through December 31, 2014. As a result, the CF for CY 2014 that was published in the CY 2014 final rule with comment period (78 FR 74230) was revised to $35.8228 for services furnished on or after January 1, 2014 and on or before December 31, 2014. The PAMA provides for a 0.0 percent update to the PFS for services furnished on or after January 1, 2015 and on or before March 31, 2015.

The Pathway for SGR Reform Act extended through March 31, 2014 several provisions of Medicare law that would have otherwise expired on December 31, 2013. The PAMA extended these same provisions further through March 31, 2015. A list of these provisions follows.

- The 1.0 floor on the work geographic practice cost index
- The exceptions process for outpatient therapy caps
- The manual medical review process for therapy services
- The application of the therapy caps and related provisions to services furnished in HOPDs

In addition, section 220 of the PAMA included several provisions affecting the valuation process for services under the PFS. Section 220(a) of the PAMA amended section 1848(c)(2) of the Act to add a new subparagraph (M). The new subparagraph (M) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of practice expense inputs; overhead and accounting information

for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS. This information may be collected or obtained through surveys of physicians or other suppliers, providers of services, manufacturers, and vendors; surgical logs, billing systems, or other practice or facility records; EHRs; and any other mechanism determined appropriate by the Secretary. If we use this information, we are required to disclose the source and use of the information in rulemaking, and to make available aggregated information that does not disclose individual eligible professionals, group practices, or information obtained pursuant to a nondisclosure agreement. Beginning with fiscal year 2014, the Secretary may compensate eligible professionals for submission of data.

Section 220(c) of the PAMA amended section 1848(c)(2)(K)(ii) of the Act to expand the categories of services that the Secretary is directed to examine for the purpose of identifying potentially misvalued codes. The nine new categories are as follows:

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

- Codes with high cost supplies.

(See section II.B. of this final rule with comment period for more information about misvalued codes.).

Section 220(i) of the PAMA also requires the Secretary to make publicly available the information we considered when establishing the multiple procedure payment reduction (MPPR) policy for the professional component of advanced imaging procedures. The policy reduces the amount paid for the professional component when two advanced imaging procedures are furnished in the same session. The policy was effective for individual physicians on January 1, 2012 and for physicians in the same group practice on January 1, 2013.

In addition, section 220 of the PAMA includes other provisions regarding valuation of services under the PFS that take effect in future years. Section 220(d) of the PAMA establishes an annual target from CY 2017 through CY 2020 for reductions in PFS expenditures resulting from adjustments to relative values of misvalued services. The target is calculated as 0.5 percent of the estimated amount of expenditures under the fee schedule for the year. If the net reduction in expenditures for the year is equal to or greater than the target for the year, the funds shall be redistributed in a budget-neutral manner within the PFS. The amount by which such reduced expenditures exceed the target for the year shall be treated as a reduction in expenditures for the subsequent year, for purposes of determining whether the target has or has not been met. The legislation includes an exemption from budget neutrality of reduced expenditures if the target is not met. Other provisions of section 220 of the PAMA include a 2-year phase-in for reductions in RVUs of at least 20 percent for potentially misvalued codes that do not involve coding changes, and certain adjustments to the fee schedule areas in California. These provisions will be addressed as we implement them in future rulemaking.

On March 5, 2014, we submitted to MedPAC an estimate of the SGR and CF applicable to Medicare payments for physicians' services for CY 2015, as required by section 1848(d)(1)(E)

of the Act. The actual values used to compute physician payments for CY 2015 will be based on later data and are scheduled to be published by November 1, 2014, as part of the CY 2015 PFS final rule with comment period.

C. Health Information Technology

The Department of Health and Human Services (HHS) believes all patients, their families, and their health care providers should have consistent and timely access to patient health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange," see http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf) HHS is committed to accelerating health information exchange (HIE) through the use of safe, interoperable health information technology (health IT), including electronic health records (EHRs), across the broader care continuum through a number of initiatives: (1) alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable HIT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs, and are designed to improve care delivery and coordination across the entire care continuum. For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs requires HIE to share summary records for more than 10 percent of care transitions. In addition, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure, ONC expressed in the 2014 Edition

Release 2 final rule (79 FR 54472-73) an intent to propose future changes to the ONC HIT Certification Program that would permit more efficient certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings.

We believe that health IT that incorporates usability features and has been certified to interoperable standards can effectively and efficiently help all providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs).

II. Provisions of the Proposed Rule for PFS

A. Resource-Based 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 physician's service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer

readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

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

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

forward are developed based entirely on the PPIS data, except as noted in this section.

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

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

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

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate

crosswalk because these specialties are more similar to each other for work time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the "All Physicians" PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

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 physician work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the

specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

d. 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.

e. 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.)

f. 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).

(1) 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.

(2) 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. This is the product of the current aggregate PE (direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data used for calculating the PE/HR by specialty.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregated 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.

(3) 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.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical PE RVUs; and the work RVUs. For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

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

(Note: For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

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

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs 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.

(4) 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 current pool of PE RVUs. 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.)

(5) 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 (MPPR). 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 the average allowed charge is used when simulating RVUs, and therefore, includes all adjustments. A time adjustment of 33 percent is made only for medical direction of two to four cases

since that is the only situation where time units are duplicative.

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

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

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

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion below.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion below.

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

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. We solicited comments regarding reliable data on maintenance costs that vary for particular equipment items. We received several comments about variable maintenance costs, which we will consider in future rulemaking. We note, however, that we do not believe that high-level summary data

from informal surveys constitutes reliable data. Rather than assertions that a particular maintenance rate is typical, multiple invoices containing equipment prices that are accompanied by maintenance contracts would provide support for a maintenance cost other than our currently assumed 5 percent. We continue to seek reliable data about variable maintenance costs, as we consider adjustments to our methodology to accommodate variable maintenance costs.

Per-use Equipment Costs: Several stakeholders have also suggested that our PE methodology should incorporate usage fees and other per-use equipment costs as direct costs. We also solicited comment on adjusting our cost formula to include equipment costs that do not vary based on the equipment time. We received a comment that addressed how to incorporate usage fees and other per-use equipment costs into our methodology, and received several comments that addressed how we should reclassify the anomalous supply inputs removed from the direct PE database. We will consider these comments in future rulemaking, including the way these anomalous supply inputs fit in to any future proposals related to per-use costs.

Interest Rate*:* In the CY 2013 final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.)

TABLE 3: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

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

	Step	Source	Formula	99213 Office visit, est Non-facility	33533 CABG, arterial, single Facility	71020 Chest x-ray Non-facility	71020-TC Chest x-ray, Non-facility	71020-26 Chest x-ray, Non-facility	93000 ECG, complete, Non-facility	93005 ECG, tracing Non-facility	93010 ECG, report Non-facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	-	5.10	5.10	-
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	0.53	0.53	-	1.19	1.19	-
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	6.92	6.92	-	0.09	0.09	-
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	85.45	13.19	13.19	-	6.38	6.38	-
(5) Direct adjustment (Dir. Adj.)	Steps 2-4	See footnote*		0.5898	0.5898	0.5898	0.5898	0.5898	0.5898	0.5898	0.5898
(6) Adjusted Labor	Steps 2-4	=Labor * Dir Adj	=(1)*(5)	7.86	45.72	3.39	3.39	-	3.01	3.01	-
(7) Adjusted Supplies	Steps 2-4	=Eqp * Dir Adj	=(2)*(5)	1.76	4.33	0.31	0.31	-	0.70	0.70	-
(8) Adjusted Equipment	Steps 2-4	=Sup * Dir Adj	=(3)*(5)	0.10	0.34	4.08	4.08	-	0.05	0.05	-
(9) Adjusted Direct	Steps 2-4		=(6)+(7)+(8)	9.72	50.40	7.78	7.78	-	3.77	3.77	-
(10) Conversion	Step 5	PFS		35.82	35.82	35.82	35.82	35.82	35.82	35.82	35.82

Factor (CF)	Step	Source	Formula	99213 Office visit, est Non-facility	33533 CABG, arterial, single Facility	71020 Chest x-ray Non-facility	71020-TC Chest x-ray, Non-facility	71020-26 Chest x-ray, Non-facility	93000 ECG, complete, Non-facility	93005 ECG, tracing Non-facility	93010 ECG, report Non-facility
(11) Adj. labor cost converted-	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.22	1.28	0.09	0.09	-	0.08	0.08	-
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.01	0.01	-	0.02	0.02	-
(13) Adj. equipment cost converted	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	-	0.01	0.11	0.11	-	-	-	-
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.27	1.41	0.22	0.22	-	0.11	0.11	-
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	-	0.22	0.17	-	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	0.82	6.67	0.53	0.53	-	0.26	0.26	-
(20) Ind. Alloc. Formula	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)

(2nd part)	Step	Source	Formula	99213 Office visit, est Non-facility	33533 CABG, arterial, single Facility	71020 Chest x-ray Non-facility	71020-TC Chest x-ray, Non-facility	71020-26 Chest x-ray, Non-facility	93000 ECG, complete, Non-facility	93005 ECG, tracing Non-facility	93010 ECG, report Non-facility
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.31	0.09	0.22	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+(21)	1.79	40.42	0.84	0.62	0.22	0.51	0.34	0.17
(23) Indirect Adjustment (Ind. Adj.)	Steps 9-11	See Footnote**		0.3813	0.3813	0.3813	0.3813	0.3813	0.3813	0.3813	0.3813
(24) Adjusted Indirect Allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.68	15.41	0.32	0.24	0.08	0.20	0.13	0.06
(25) Ind. Practice Cost Index (IPCI)	Steps 12-16			1.07	0.75	0.99	0.99	0.99	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24)*(25)	0.73	11.59	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	13.04	0.54	0.46	0.08	0.29	0.23	0.06

Note: PE RVUs in Table 5, row 27, may not match Addendum B due to rounding.
*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] =

	Step	Source	Formula	99213 Office visit, est Non-facility	33533 CABG, arterial, single Facility	71020 Chest x-ray Non-facility	71020-TC Chest x-ray, Non-facility	71020-26 Chest x-ray, Non-facility	93000 ECG, complete, Non-facility	93005 ECG, tracing Non-facility	93010 ECG, report Non-facility

[step9]/[step10]

Note: The use of any particular conversion factor (CF) in Table 5 to illustrate the PE Calculation has no effect on the resulting RVUs.

Note: The Other Adjustment includes an adjustment for the equipment utilization change.

3. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2015 revisions related to direct PE inputs for specific services. The final direct PE inputs are included in the final rule CY 2015 direct PE input database, which is available 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.

a. RUC Recommendation for Monitoring Time following Moderate Sedation

We received a recommendation from the RUC regarding appropriate clinical labor minutes for post-procedure moderate sedation monitoring and post-procedure monitoring. The RUC recommended 15 minutes of RN time for one hour of monitoring following moderate sedation and 15 minutes of RN time per hour for post-procedure monitoring (unrelated to moderate sedation). For 17 procedures listed in Table 5, the recommended clinical labor minutes differed from the clinical labor minutes in the direct PE database. We proposed to accept, without refinement, the RUC recommendation to adjust these clinical labor minutes as indicated in Table 5 as "Change to Clinical Labor Time."

TABLE 5: Codes with Changes to Post-Procedure Clinical Labor Monitoring Time

CPT Code	Current Monitoring Time (Min)	RUC Recommended Total Post-Procedure Monitoring Time (Min)	Change to Clinical Labor Time (Min)
32553	30	60	30
35471	21	60	39
35475	60	30	-30
35476	60	30	-30
36147	18	30	12
37191	60	30	-30
47525	6	15	9
49411	30	60	30
50593	30	60	30
50200	15	60	45
31625	20	15	-5
31626	25	15	-10
31628	25	15	-10
31629	25	15	-10
31634	25	15	-10
31645	10	15	5
31646	10	15	5

Comment: We received two comments supporting our proposal to accept the RUC recommendation, without refinement, to adjust the clinical labor minutes as indicated in Table 5. One commenter noted that the RUC recommendation was a more accurate reflection of the monitoring time, particularly for codes 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) and 50200 (Renal biopsy; percutaneous, by trocar or needle), than the current time.

Response: We appreciate commenters' support for our proposal. After consideration of comments received, we are finalizing our proposal to accept, without refinement, the RUC recommendation to adjust the clinical labor minutes as indicated in Table 5 as "Change to Clinical Labor Time."

b. RUC Recommendation for Standard Moderate Sedation Package

We received a RUC recommendation to modify PE inputs included in the standard moderate sedation package. Specifically, the RUC indicated that several specialty societies have pointed to the need for a stretcher during procedures for which moderate sedation is inherent in the procedure. Although the RUC did not recommend that we make changes to PE inputs for codes at this time, the RUC indicated that its future recommendations would include the stretcher as a direct input for procedures including moderate sedation.

The RUC recommended three scenarios that it would use in the future to allocate the equipment time for the stretcher based on the procedure time and whether the stretcher would be available for other patients to use during a portion of the procedure. Although we appreciate the RUC's attention to the differences in the time required for the stretcher based on the time for the procedure, we believe that one of the purposes of standard PE input packages is to reduce the complexity associated with assigning appropriate PE inputs to individual procedures while, at the same time, maintaining relativity between procedures. Since we generally allocate inexpensive equipment items to the entire service period when they are likely to be unavailable for another use during the full service period, we believe it is preferable to treat the stretcher consistently across services. Therefore, we proposed to modify the standard moderate sedation input package to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. The revised moderate sedation input package will be applied to relevant codes as we review them through future notice and comment rulemaking. In seeking comments on the proposal, we stated that it would be useful to hear stakeholders' views and the reasoning behind them on this issue, especially from those who think that the stretcher, as expressed through the allocation of equipment minutes, should be allocated with more granularity than the equipment costs that are allocated to other similar items.

Comment: We received comments supporting our proposal to add the stretcher to the moderate sedation package, including support to include the stretcher for the same length of time as the other equipment items included in the moderate sedation package since it is used by the patient for the duration of their recovery and not available to other patients during that time.

Response: We appreciate the commenters' support for our proposal. After consideration of comments received, we are finalizing our proposal to add the stretcher to the moderate sedation package for the same length of time as the other equipment items in the moderate sedation package. We note that we will not apply this change retroactively, but will make the change to the moderate sedation package for codes being finalized for 2015, as well as interim final codes for 2015. For a detailed discussion of the specific codes impacted by this change, we refer readers to sections II.F. of this final rule with comment period.

c. RUC Recommendation for Migration from Film to Digital Practice Expense Inputs

The RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove a list of supply and equipment items associated with film technology since these items are no longer a typical resource input; these items are detailed in Table 6. 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. We received a description of the PACS system as part of the recommendation, which included both items that appear to be direct PE items and items for which indirect PE RVUs are allocated in the PE methodology. As we have previously indicated, items which are not clinical labor, medical supplies, or medical equipment, or are not individually allocable to a particular patient for a particular procedure, are not categorized as direct costs in the PE methodology. Since we did not receive any invoices for

the PACS system prior to the proposed rule, we were unable to determine the appropriate pricing to use for the inputs. We proposed to accept the RUC recommendation to remove the film supply and equipment items, and to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense. Specifically, for the 31 services that already contain ED021 (computer, desktop, w-monitor), we proposed to retain the time that is currently included in the direct PE input database. For the remaining services that are valued in the nonfacility setting, we proposed to allocate the full clinical labor intraservice time to ED021, except for codes without clinical labor, in which case we proposed to allocate the intraservice work time to ED021. For services valued only in the facility setting, we proposed to allocate the post-service clinical labor time to ED021, since the film supply and/or equipment inputs were previously associated with the post-service period.

TABLE 6: RUC-Recommended Supply and Equipment Items Removed for Digital Imaging Services

CMS Code	Description
SK013	computer media, dvd
SK014	computer media, floppy disk 1.44mb
SK015	computer media, optical disk 128mb
SK016	computer media, optical disk 2.6gb
SK022	film, 8inx10in (ultrasound, MRI)
SK025	film, dry, radiographic, 8in x 10in
SK028	film, fluoroscopic 14 x 17
SK033	film, x-ray 10in x 12in
SK034	film, x-ray 14in x 17in
SK035	film, x-ray 14in x 36in
SK037	film, x-ray 8in x 10in
SK038	film, x-ray 8in x 10in (X-omat, Radiomat)
SK086	video tape, VHS
SK089	x-ray developer solution
SK090	x-ray digitalization separator sheet
SK091	x-ray envelope
SK092	x-ray fixer solution
SK093	x-ray ID card (flashcard)
SK094	x-ray marking pencil
SK098	film, x-ray, laser print
SM009	cleaner, x-ray cassette-screen
ED014	computer workstation, 3D reconstruction CT-MR
ED016	computer workstation, MRA post processing
ED023	film processor, PET imaging
ED024	film processor, dry, laser
ED025	film processor, wet
ED027	film processor, x-omat (M6B)
ER018	densitometer, film
ER029	film alternator (motorized film viewbox)
ER067	x-ray view box, 4 panel

We note that the RUC exempted certain procedures from its recommendation because (a) the dominant specialty indicated that digital technology is not yet typical or (b) the procedure only contained a single input associated with film technology, and it was determined that the sharing of images, but not actual imaging, may be involved in the service. However, we do not believe that the most appropriate approach in establishing relative values for services that

involve imaging is to exempt services from the transition from film to digital PE inputs based on information reported by individual specialties. Although we understand that the migration from film technology to digital technology may progress at different paces for particular specialties, we do not have information to suggest that the migration is not occurring for all procedures that require the storage of images. Just as it was appropriate to use film inputs as a proxy for some services for which digital inputs were typical pending these changes in the direct PE input database, we believe it is appropriate to use digital inputs as a proxy for the services that may still use film, pending their migration to digital technology. In addition, since the RUC conducted its collection of information from the specialties over several years, we believe the migration process from film to digital inputs has likely continued over the time period during which the information was gathered, and that the digital PE inputs will reflect typical use of technology for most if not all of these services before the change to digital inputs would take effect beginning January 1, 2015.

We noted that we believed that, for the sake of relativity, we should remove the equipment and supply inputs noted below from all procedures in the direct PE database, including those listed in Table 7. We sought comment on whether the computer workstation, which we proposed to use as a proxy for the PACS workstation, is the appropriate input for the services listed in Table 7, or whether an alternative input is a more appropriate reflection of direct PE costs.

TABLE 7: Codes Containing Film Inputs But Excluded From the RUC Recommendation

HCPCS	Short Descriptor
21077	Prepare face/oral prosthesis
28293	Correction of bunion
61580	Craniofacial approach skull
61581	Craniofacial approach skull
61582	Craniofacial approach skull
61583	Craniofacial approach skull
61584	Orbitocranial approach/skull
61585	Orbitocranial approach/skull
61586	Resect nasopharynx skull
64517	N block inj hypogas plxs
64681	Injection treatment of nerve
70310	X-ray exam of teeth
77326	Brachytx isodose calc simp
77327	Brachytx isodose calc interm
77328	Brachytx isodose plan compl
91010	Esophagus motility study
91020	Gastric motility studies
91034	Gastroesophageal reflux test
91035	G-esoph reflx tst w/electrod
91037	Esoph imped function test
91038	Esoph imped funct test > 1hr
91040	Esoph balloon distension tst
91120	Rectal sensation test
91122	Anal pressure record
91132	Electrogastrography
91133	Electrogastrography w/test
92521	Evaluation of speech fluency
92523	Speech sound lang comprehend

HCPCS	Short Descriptor
92524	Behavioral qualit analys voice
92601	Cochlear implt f/up exam <7
92603	Cochlear implt f/up exam 7/>
92611	Motion fluoroscopy/swallow
92612	Endoscopy swallow tst (fees)
92614	Laryngoscopic sensory test
92616	Fees w/laryngeal sense test
95800	Slp stdy unattended
95801	Slp stdy unatnd w/anal
95803	Actigraphy testing
95805	Multiple sleep latency test
95806	Sleep study unatt&resp efft
95807	Sleep study attended
95808	Polysom any age 1-3> param
95810	Polysom 6/> yrs 4/> param
95811	Polysom 6/>yrs cpap 4/> parm
95812	Eeg 41-60 minutes
95813	Eeg over 1 hour
95829	Surgery electrocorticogram
95950	Ambulatory eeg monitoring
95953	Eeg monitoring/computer
95954	Eeg monitoring/giving drugs
95955	Eeg during surgery
95956	Eeg monitor technol attended
95957	Eeg digital analysis
96904	Whole body photography
G0270	Mnt subs tx for change dx
G0271	Group mnt 2 or more 30 mins

Finally, we noted that the RUC recommendation also indicated that, given the labor-intensive nature of reviewing all clinical labor tasks associated with film technology, these times would be addressed as these codes are reviewed. We agreed with the RUC that reviewing and adjusting the times for each code would be difficult and labor-intensive since the direct PE input database does not allow for a comprehensive adjustment of the clinical labor time based on changes in particular clinical labor tasks. To make broad adjustments such as this across codes, the PE database would need to contain the time associated with individual clinical labor tasks rather than reflecting only the sum of times for the pre-service period, service period, and post-service period, as it does now. We recognized this situation presents a challenge in implementing RUC recommendations such as this one, and makes it difficult to understand the basis of both the RUC's recommended clinical labor times and our refinements of those recommendations. Therefore, we stated that we were considering revising the direct PE input database to include task-level clinical labor time information for every code in the database. As an example, we referred readers to the supporting data files for the direct PE inputs, which include public use files that display clinical labor times as allocated to each individual clinical labor task for a sample of procedures. We displayed this information as we attempt to increase the transparency of the direct PE database. We stated that we hoped that this modification would enable us to more accurately allocate equipment minutes to clinical labor tasks in a more consistent and efficient manner. Given the number of procedures and the volume of information involved, we sought comments on the feasibility of this approach. We note that we did not propose to make any changes to PE inputs for CY 2015 based on this modification to the design of the direct PE input database.

As discussed in section II.G. of this final rule with comment period, some of the RUC recommendations for 2015 included film items as practice expense inputs. For existing codes,

the database from the proposed rule already included the PACS workstation proxy. However, for new services, as with the current items in the database, we have replaced the film items with the PACS workstation proxy. The codes affected by this change are listed in Table 8.

TABLE 8: 2015 Codes Affected by Removal of Film Inputs

HCPCS	Short Descriptor	HCPCS	Short Descriptor
22510	Perq cervicothoracic inject	93314	Echo transesophageal
22511	Perq lumbosacral injection	93320	Doppler echo exam heart
22513	Perq vertebral augmentation	93321	Doppler echo exam heart
22514	Perq vertebral augmentation	93325	Doppler color flow add-on
62302	Myelography lumbar injection	93880	Extracranial bilat study
62303	Myelography lumbar injection	93882	Extracranial uni/ltd study
62304	Myelography lumbar injection	93886	Intracranial complete study
62305	Myelography lumbar injection	93888	Intracranial limited study
71275	Ct angiography chest	93895	Carotid intima atheroma eval
72191	Ct angiograph pelv w/o&w/dye	93925	Lower extremity study
72240	Myelography neck spine	93926	Lower extremity study
72255	Myelography thoracic spine	93930	Upper extremity study
72265	Myelography l-s spine	93931	Upper extremity study
72270	Myelogphy 2/> spine regions	93970	Extremity study
74174	Ct angio abd&pelv w/o&w/dye	93971	Extremity study
74175	Ct angio abdom w/o & w/dye	93975	Vascular study
74230	Cine/vid x-ray throat/esoph	93976	Vascular study
76942	Echo guide for biopsy	93978	Vascular study
93312	Echo transesophageal	93979	Vascular study

Comment: We received many comments on our proposal to remove the equipment and supply inputs associated with film technology from the direct PE database. In general, commenters supported our proposal to remove the film inputs from the direct PE database. Some commenters supported our use of the desktop computer as a proxy for the PACS workstation, but other commenters opposed using this item as a proxy. Commenters opposed to using the desktop computer as the proxy item stated that the PACS workstation was significantly more expensive and included greater functionality than a desktop computer. Some commenters opposed our proposal to

maintain the current equipment time allocated to the computer desktop for the 31 services that already included this equipment item, suggesting that it was incorrect to eliminate the film inputs without proportionately increasing the proxy time for ED021. Some commenters requested a delay in implementation until stakeholders provide invoices or otherwise work with CMS to identify prices for the PACS items. Some commenters suggested CMS should develop a means to allocate digital technology costs to individual services, even if it is difficult to do so. Another commenter explained that it is difficult for stakeholders to obtain invoices that display prices for individual items, such as the PACS workstation, since the price of the particular items is often bundled with other related equipment and services. Many commenters urged CMS to work with stakeholders to obtain invoices, while other commenters requested that CMS accept the RUC recommendation regarding the PACS workstation.

Response: We appreciate commenters' support for our proposal to incorporate the transition from film to digital imaging technology into the direct PE input database. With regard to the pricing of the PACS workstation, as with all inputs, we would prefer to use actual paid invoices to establish the input price. However, in the absence of invoices demonstrating the actual cost, we believe that use of a proxy to price the appropriate inputs, in this case the PACS workstation, is preferable to continuing to use inputs that we know are no longer typical. We made the proposal to use the computer, desktop, w-monitor (ED021), priced at $2,501, as a proxy based on our assessment of similar resource costs between the item and the PACS workstation. Although some commenters stated that the item was not an appropriate proxy, these commenters did not provide any evidence to indicate that the resource costs are not similar or to suggest a more appropriate proxy. Nor were any paid invoices submitted. Absent such

information, we continue to believe that using the proxy item is the best approach to incorporate the direct PE cost of the digital imaging technology.

With regard to the 31 services that already included the desktop computer as an equipment input, we will include the desktop computer as a proxy for the PACS workstation using the same methodology as for the services that did not previously contain the desktop computer. To clearly differentiate the desktop computer proxy from the desktop computer currently included in these services, and to facilitate accurate replacement of this input when we do receive pricing information, we will create a new equipment item called "desktop computer (proxy for PACS workstation)," which will be allocated to each procedure using the methodology described above.

Comment: Some commenters opposed our removal of the film inputs from services that were not included in the RUC recommendation, but did not provide a rationale for their opposition.

Response: For the reasons we explained in making the proposal and reiterate above, we continue to believe that it is appropriate to remove these items from the direct PE database.

Comment: Some commenters provided specific suggestions regarding the use of digital inputs should CMS decide to move forward with the proposal. Commenters requested that for portable x-ray services, CMS include a flat plate receptor/image capture plate to capture the image, specialized software to process the image, and multiple high definition monitors used by the interpreting radiologist. Commenters provided an invoice for the image capture plate at a price of $25,600 indicating that this item replaces the film as the media to record the image.

Response: We appreciate that commenters provided us with an invoice for the

image capture plate. However, services furnished by portable x-ray providers are reported using the same procedure codes as services provided using fixed machines. Since the typical x-ray service is furnished using fixed equipment, we are not including the image capture plate that is associated with portable equipment as an input for the imaging procedure codes. We also do not believe that high definition monitors used by the interpreting radiologist are appropriately included in the technical component of imaging procedures; rather, these are indirect costs associated with the professional component of the service. Therefore, we are not including the high definition monitors as an input for these services. Finally, to determine whether the software is appropriately categorized as a direct PE input, we need more information about the functionality of the software, and whether it is used in furnishing the typical x-ray service (including services furnished using fixed machinery). Until we have information that supports the inclusion of this item as a direct cost, we will not include the software for x-ray services.

Comment: Commenters were supportive of the increased transparency with regard to the direct PE inputs, but several commenters suggested that there may be more feasible approaches to break out the individual clinical labor tasks associated with each portion of the service (pre-service period, service period, and post-service period). The RUC suggested that we post all PE worksheets and supporting materials in code-order on our website. Other commenters did not suggest a specific alternative approach to providing detail for the individual clinical labor tasks.

Response: We appreciate the RUC's suggestion regarding the posting of the PE worksheets, but we do not believe that this would enable us to accomplish a comprehensive cross-code analysis and refinement to clinical labor times within the direct PE input database to increase consistency for identical clinical labor tasks between codes. Since we did not receive other suggestions from commenters on an approach to break out the individual clinical labor

tasks associated with each service period to enable us to conduct the necessary analysis, we will pursue the approach described in the proposed rule. We will consider the comments submitted and continue to work with interested stakeholders regarding the best approaches to displaying the supporting files. We note that public use files continue to be available in the same format as in previous years, but that additional public use files now display the clinical labor tasks for each service period, providing greater transparency and enabling comparisons across codes. We note that we have refined the file structure based on comments, and we continue to seek input on whether there are additional or alternative ways to display this information to enhance its clarity, and note that there are challenges inherent in the display of this information in a two-dimensional format. We refer readers to the public use files available 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

d. Inputs for Digital Mammography Services

Mammography services are currently reported and paid using both CPT codes and G-codes. To meet the requirements of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), we established G-codes for use beginning in CY 2002 to pay for mammography services using new digital technologies (G0202 screening mammography digital; G0204 diagnostic mammography digital; G0206 diagnostic mammography digital). We continued to use the CPT codes for mammography services furnished using film technology (77055 (Mammography; unilateral); 77056 (Mammography; bilateral); 77057 (Screening mammography, bilateral (2-view film study of each breast)). As we discussed previously in this section, the RUC has recommended that all imaging codes, including mammography, be valued using digital rather than film inputs because the use of film is no longer typical. A review of Medicare claims data shows that the mammography CPT codes are billed extremely

infrequently, and that the G-codes are billed for the vast majority of mammography claims, confirming the RUC's conclusion that the typical service uses digital technology. As such, we stated that we do not believe there is a reason to continue the separate CPT codes and G-codes for mammography services since both sets of codes would have the same values when priced based upon the typical digital technology. Accordingly, we proposed to delete the mammography G-codes beginning for CY 2015 and to pay all mammography using the CPT codes.

We indicated that, although we believed that the CPT codes should now be used to report all mammography services, we had concerns about whether the current values for the CPT codes accurately reflect the resource inputs associated with furnishing the services. Because the CPT codes have not been recently reviewed and significant technological changes have occurred since the current values were established, we did not believe it would be appropriate to retain the current values for the CPT codes. Therefore, we proposed to value the CPT codes using the RVUs previously established for the G-codes. We believed these values would be most appropriate since they were established to reflect the use of digital technology, which is now typical.

As discussed in section II.B of this final rule with comment period, we proposed these CPT codes as potentially misvalued and requested that the RUC and other interested stakeholders review these services in terms of appropriate work RVUs, work time assumptions, and direct PE inputs. However, as discussed in section II.B. of this final rule with comment period, we will continue to maintain separate payment rates for film and digital mammography while we consider revaluation of all mammography services. For CY 2015, we will therefore maintain both the G-codes and CPT codes; we will continue using the 2014 RVUs from each of the following codes to price them for 2015: G0202, G0204, G0206, 77055, 77056, and 77057.

2015. We also note that we will continue to pay for film mammography services at the 2014 rates until we revalue the mammography services.

We refer readers to section II.B. of this final rule with comment period, where we address comments received on this proposal.

e. Radiation Treatment Vault

In previous rulemaking (77 FR 68922, 78 FR 74346), we indicated that we included the radiation treatment vault as a direct PE input for several recently reviewed radiation treatment codes for the sake of consistency with its previous inclusion as a direct PE input for some other radiation treatment services, but that we intended to review the radiation treatment vault input and address whether or not it should be included in the direct PE input database for all services in future rulemaking. Specifically, we questioned whether it was consistent with the principles underlying the PE methodology to include the radiation treatment vault as a direct cost given that it appears to be more similar to building infrastructure costs than to medical equipment costs. In response to this discussion, we received comments and invoices from stakeholders who indicated that the vault should be classified as a direct cost. However, upon review of the information received, we believed that the specific structural components required to house the linear accelerator are similar in concept to components required to house other medical equipment such as expensive imaging equipment. In general, the electrical, plumbing, and other building specifications are often unique to the intended functionality of a given building, including costs that are attributable to the specific medical equipment housed in the building, but those building characteristics do not represent direct medical equipment costs in our established PE methodology. Therefore, we believed that the special building requirements indicated for the radiation treatment vault to house a linear accelerator do not represent a direct cost in our PE methodology, and that the vault construction is instead accounted for in the indirect PE

methodology, just as the building and infrastructure costs are treated for other PFS services including those with specialized infrastructure costs to accommodate specific equipment. Therefore, we proposed to remove the radiation treatment vault as a direct PE input from the radiation treatment procedures listed in Table 9, because we believed that the vault is not, itself, medical equipment; and therefore, it is accounted for in the indirect PE methodology.

TABLE 9: HCPCS Codes Affected by Proposed Removal of Radiation Treatment Vault

HCPCS	Short Descriptor
77373	Sbrt delivery
77402	Radiation treatment delivery
77403	Radiation treatment delivery
77404	Radiation treatment delivery
77406	Radiation treatment delivery
77407	Radiation treatment delivery
77408	Radiation treatment delivery
77409	Radiation treatment delivery
77411	Radiation treatment delivery
77412	Radiation treatment delivery
77413	Radiation treatment delivery
77414	Radiation treatment delivery
77416	Radiation treatment delivery
77418	Radiation tx delivery imrt

Comment: We received many comments regarding our proposal to remove the radiation treatment vault as a direct cost from the radiation treatment delivery codes. Although one commenter supported the proposal, most commenters opposed the proposal. In general, commenters reiterated their rationale for inclusion of the vault as a direct practice expense input, asserting that the vault is necessary for the functioning of the equipment, serves a unique medical need, cannot be separated from the treatment delivered by the linear accelerator, and cannot be repurposed for another use. Commenters also stated that the Internal Revenue Code treats the vault as medical equipment that is separately depreciable from the building itself. For the most part, commenters objected to the removal of the vault given the context of declining

Medicare payment for radiation oncology services over the past few years, or in conjunction with the revised radiation treatment code set. Specifically, several commenters suggested that stakeholders cannot provide meaningful comment about the impact of the vault proposal in the context of other pending changes. Some commenters requested a phase-in of any decrease in payment so that providers of radiation therapy services have an opportunity to adjust their practice costs. Several commenters also suggested that the change in payment could exacerbate problems in access to oncology services for Medicare patients.

Response: We appreciate commenters' concerns regarding the proposal to remove the vault as a direct practice expense input. We understand the essential nature of the vault in the provision of radiation therapy services and its uniqueness to a particular piece of medical equipment but are not convinced that either of these factors leads to the conclusion that the vault should be considered medical equipment for purposes of the PE methodology under the PFS. We appreciate the information commenters provided regarding the IRS treatment of the vault under tax laws, but the purposes and goals of the tax code and the PFS PE methodology are different, and, as such, attempts to draw parallels between the two are not necessarily instructive or relevant. We are not finalizing our proposal at this time, but intend to further study the issues raised by the vault and how it relates to our PE methodology.

Comment: A commenter noted that removing the vault as a direct cost also reduces the amount of indirect PE allocated for these procedures, and that this proposal does not shift the vault from direct PE to indirect PE, but rather drops the cost of the vault entirely. Another commenter stated that since the pool of indirect PE RVUs associated with radiation oncology services is fixed, the issue in question is how the indirect costs involved in furnishing treatment services compare to the indirect costs in providing other radiation oncology services.

Response: We understand the concerns of commenters regarding the importance of ensuring that the costs related to the vault are included in the PE methodology. We want to point out, however, that within the established PE methodology, the allocation of indirect PE to individual codes has significant impact on the PE RVUs that determine Medicare payment for individual services. In other words, we believe it is important for stakeholders to recognize that practice expense costs not included in the direct PE input database contribute to the development of PE RVUs through the data used to allocate indirect PE RVUs. We also want to point out that the pool of indirect PE RVUs is not fixed at the specialty level. Rather, the pool of indirect costs under the entire PFS is maintained from year to year, as delineated in step 11 of the PE methodology above. Therefore, changes in the allocation of indirect PE for particular PFS services based on changes in either direct PE inputs, work RVUs, work time, or utilization data, impacts the amount of indirect PE allocated to all other PFS services , not just those furnished by specialties that furnish that service.

After continued review of the issues pertaining to the vault in the context of the comments, we believe that these issues require further study. Therefore, at this time, we will continue to include the vault as a direct PE input for the services listed in Table 9.

f. Clinical Labor Input Errors

Subsequent to the publication of the CY 2014 PFS final rule with comment period, it came to our attention that, due to a clerical error, the clinical labor type for CPT code 77293 (Respiratory Motion Management Simulation (list separately in addition to code for primary procedure)) was entered as L052A (Audiologist) instead of L152A (Medical Physicist), which has a higher cost per minute. We proposed a correction to the clinical labor type for this service.

Comment: Commenters appreciated our proposal to correct this error.

Response: We appreciate commenters' support for our proposal, and are finalizing the assignment of clinical labor type L152A to code 77293 as proposed. The CY 2015 Direct Practice Expense Input database reflects this correction.

In conducting a routine data review of the database, we also discovered that, due to a clerical error, the RN time allocated to CPT codes 33620 (Apply r&l pulm art bands), 33621 (Transthor cath for stent), and 33622 (Redo compl cardiac anomaly) was entered in the nonfacility setting, rather than in the facility setting where the code is valued. When a service is not valued in a particular setting, any inputs included in that setting are not included in the calculation of the PE RVUs for that service. Therefore, we proposed to move the RN time allocated to these procedures to the facility setting. The PE RVUs listed in Addendum B reflect these technical corrections.

We did not receive any comments on this proposal; therefore, we are finalizing our proposal to move the RN time allocated to these procedures to the facility setting. The CY 2015 Direct Practice Expense Input database reflects this correction.

g. Work Time

Subsequent to the publication of the CY PFS 2014 final rule with comment period, several inconsistencies in the work time file came to our attention. First, for some services, the total work time, which is used in our PE methodology, did not equal the sum of the component parts (pre-service, intra-service, post-service, and times associated with global period visits). The times in the CY 2015 work time file reflect our corrected values for total work time. Second, for a subset of services, the values in the pre-positioning time, pre-evaluation time, and pre-scrub-dress-wait time, were inadvertently transposed. We note that this error had no impact on calculation of the total times, but has been corrected in the CY 2015 work time file. Third, minor discrepancies for a series of interim final codes were identified between the work time file and

the way we addressed these codes in the preamble text. Therefore, we have made adjustments to the work time file to reflect the decisions indicated in the preamble text. The work time file is available on the CMS website under the supporting data files for the CY 2015 PFS final rule with comment period at http://www.cms.gov/PhysicianFeeSched/. Note that for comparison purposes, the CY 2014 work time file is located at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1600-FC.html.

Comment: A commenter supported our proposal to correct the work times associated with the procedures affected by this proposal.

Response: We appreciate the commenter's support for our proposal. After consideration of the comment received, we are finalizing our proposal to adjust the work time file as proposed. The work time file is available on the CMS website under the supporting data files for the CY 2015 PFS final rule with comment period at http://www.cms.gov/PhysicianFeeSched/

h. 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 2013, we received a request to update the price of SD216 (catheter, balloon, esophageal or rectal (graded distention test)) from $217 to $237.50. We also received a request to update the price of SL196 (kit, HER-2/neu DNA Probe) from $105 to $144.50. We received invoices that documented updated pricing for each of these supply items. We proposed to increase the price associated with these supply items.

We continue to believe it is important to maintain a periodic and transparent process to update the price of items to reflect typical market prices in our ratesetting methodology, and we

continue to study the best way to improve our current process. We remind stakeholders that we have difficulty obtaining accurate pricing information. The goal of the current transparent process is to offer the opportunity for the community to both request supply price updates by providing us copies of paid invoices, and to object to proposed changes in price inputs for particular items by providing additional information about prices available to the practitioner community. We remind stakeholders that PFS payment rates are developed within a budget neutral, relative value system, and any increases in price inputs for particular supply items result in corresponding decreases to the relative values of all other direct PE inputs.

We also received a RUC recommendation to update the prices associated with two supply items. Specifically, the RUC recommended that we increase the price of SA042 (pack, cleaning and disinfecting, endoscope) from $15.52 to $17.06 to reflect the addition of supply item SJ009 (basin, irrigation) to the pack, and increase the price of SA019 (kit, IV starter) from $1.37 to $1.60 to reflect the addition of supply item SA044 (underpad 2 ft. x 3 ft. (Chux)) to the kit. We proposed to update the prices for both of these items based on these recommendations.

Comment: We received several comments regarding our concern about obtaining accurate pricing information for equipment and supply items included in the direct PE database. The RUC indicated that it would continue to work with specialty societies to obtain paid invoices. A commenter suggested that a sample of paid invoices be obtained from practices and submitted with the PE materials to the RUC, or directly to CMS. Another commenter expressed concern regarding CMS's assertion that invoices are difficult to obtain, given that the RUC process collects lists of resources required to furnish services in the physician office using a standardized process that is typically accompanied by invoices. Another commenter stated that CMS used only the lowest-cost invoice for a particular equipment item since the other invoices

included "soft costs," and that CMS should establish an approach that would allow invoices to be used even if they contain "soft costs."

Response: We appreciate the RUC's assistance in obtaining paid invoices from the specialty societies. These invoices are helpful in pricing inputs. We disagree that we use the lowest-cost invoice because it had the lowest cost; rather, we often use the lowest-cost invoice because we do not have a method to use invoices that include costs that are not included as part of the equipment costs, so called "soft costs," within the PE methodology. We do not believe it would serve accuracy or relativity to include as part of the pricing inputs "soft costs" that increase the price of particular supply or equipment items. We would welcome further input on potential approaches for "backing out" these costs.

Comment: One commenter disagreed with CMS's position that the RUC PE Subcommittee's review results in biased or inaccurate resource input costs because the prices are largely maintained in the direct PE input database by CMS.

Response: Although we did not raise this point in the CY 2015 PFS proposed rule, we refer readers to our discussion in previous rulemaking (for example, the CY 2011 PFS final rule with comment period at 75 FR 73250 and the CY 2014 PFS final rule with comment period at 78 FR 74246) regarding issues associated with obtaining appropriate prices for medical equipment and supply items included in the direct PE database. We note that the RUC provides recommendations regarding the use of particular items in furnishing a service, but does not provide CMS with recommendations regarding the prices of direct PE item. Without assigning a price, the input cannot be factored in to our PE RVU methodology. Our price information is almost exclusively anecdotal, and generally updated only through voluntary submission of a small number of invoices from the same practitioners that furnish and are paid for the services

that use the particular inputs. Therefore, we continue to believe there is potential for bias in the information we receive.

Comment: In its comment, the RUC suggested that an annual CMS review of paid invoices for high-cost supplies would be appropriate. A commenter referenced comments made on the CY 2014 PFS final rule with comment period, and expressed agreement with those commenters that the provision of pricing information is sensitive because of issues involving proprietary pricing information and price negotiations for individual practitioners. This commenter also agreed with CMS that such information would be less sensitive if it confirmed inputs contained in the direct PE database. However, the commenter noted that requiring paid invoices from this point forward only partially addresses the concern since many existing inputs are not based on paid invoices; specifically, societies working on inputs for new, revised, or potentially misvalued services are disadvantaged in comparison to many existing inputs due to fee schedule relativity. The commenter suggested that CMS may need to undertake a comprehensive review of all direct PE inputs and obtain paid invoices to systematically address its concerns.

Response: We share commenters' concerns that codes that are being reviewed may be disadvantaged relative to codes that contain input prices that may not be based on paid invoices; and note that we rely on the public process to ensure continued relativity within the direct PE inputs. We encourage interested stakeholders to review updates to prices, as well as prices for new items, to ensure that they appear reasonable and current, and to provide us with updated pricing information, particularly regarding high cost supplies that have a greater impact on relativity. We refer readers to section II.F. of this final rule with comment period, in which we detail price updates, as well as establish new prices, for inputs included in new, revised, and potentially misvalued codes.

Comment: We received some comments in support of our proposal to update the price for SL196 (kit, HER-2/neu DNA Probe).

Response: We appreciate the commenters' support for our proposal to update the price for SL196. After publication of our proposal, we obtained new information suggesting that further study of the price of this item is necessary before proceeding to update the input price. Therefore, we are not finalizing our proposal to update the price for SL196, and will consider this matter in future rulemaking.

Comment: We did not receive any comments regarding our proposal to update the price for of SD216 (catheter, balloon, esophageal or rectal (graded distention test)).

Response: We are finalizing the price updates for SD216.

Comment: We received comments in support of the price update to SA019 (kit, IV starter) and SA042 (pack, cleaning and disinfecting, endoscope).

Response: We appreciate the commenters' support for our proposal to update the price for SA019 and SA042. After consideration of comments received, we are finalizing the price updates for SA019 and SA042.

i. New Standard Supply Package for Contrast Imaging

The RUC recommended creating a new direct PE input standard supply package "Imaging w/contrast, standard package" for contrast enhanced imaging, with a price of $6.82. This price reflects the combined prices of the medical supplies included in the package; these items are listed in Table 10. We proposed to accept this recommendation, but sought comment on whether all of the items included in the package are used in the typical case. The CY 2015 direct PE database reflects this change and is available on the CMS website under the supporting data files for the CY 2015 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/.

TABLE 10: Standard Contrast Imaging Supply Package

Medical Supply Description	CMS Supply Code	Unit	Quantity	Price
Kit, IV starter	SA019	Kit	1	$1.60
Gloves, non-sterile	SB022	Pair	1	0.084
Angiocatheter 14g-24g	SC001	Item	1	1.505
Heparin lock	SC012	Item	1	0.917
IV tubing (extension)	SC019	Foot	3*	1.590
Needle, 18-27g	SC029	Item	1	0.089
Syringe 20ml	SC053	Item	1	0.558
Sodium chloride 0.9% inj. bacteriostatic (30ml uou)	SH068	Item	1	0.700
Swab-pad, alcohol	SJ053	Item	1	0.013
TOTAL				**$7.06**

* The price for SC019 (IV tubing, (extension)) is $0.53 per foot.

Comment: Commenters supported our proposal to create the standard supply package for contrast imaging. Some commenters expressed concern that the proposed supply package did not include the full range of supplies typically used when performing contrast imaging. One commenter stated that, for echocardiography labs that utilize contrast-enhanced ultrasound, additional items are typically part of the contrast imaging supply package, including 2x2 gauze pads, a stopcock, and tape. Another commenter suggested that a power injector should also be included in the standard contrast imaging supply package. Commenters also noted that CMS provided limited information regarding how the prices were assigned to the supply items, and pointed to discrepancies between the direct PE database files and the prices quoted in the table.

Response: We appreciate commenters' support for our proposal. We note that the RUC recommendation for the standard contrast imaging supply package also noted that the inputs for CTA and MRA studies would include the standard contrast imaging supply pack in addition to a stop cock (SC050) and additional tubing. While we acknowledge a commenter's suggestion that additional items may be used when echocardiography labs conduct contrast-enhanced ultrasound studies, we do not have information to suggest that these items are used for other imaging studies, such as CT and MRI contrast-enhanced studies. We would welcome more information

on whether these items should be included in the newly created standard contrast imaging kit, as well as whether the power injector is used whenever the other inputs in the standard contrast imaging supply package are used, or whether they are used only in certain instances. We note that the reason for the discrepancy in the price for the IV starter kit is that we proposed to update the price at the same time that we proposed to create a new contrast imaging kit. Since we are finalizing the price update for SA019 (kit, IV starter), we are also finalizing a revised price for the new standard contrast imaging package of $7.06. Finally, we disagree with the commenter's suggestion that CMS provided limited information about the pricing for the items included in the kit, as these items are existing inputs in the direct PE database, and the codes associated with these items were listed in the table in the proposed rule. After consideration of comments received, we are finalizing our proposal to create a standard contrast imaging supply pack, with a revised price of $7.06.

j. Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

In the CY 2014 PFS final rule with comment period (78 FR 74245), we summarized comments received about whether CPT codes 77372 and 77373 would accurately reflect the resources used in furnishing the typical SRS delivery if there were no coding distinction between robotic and non-robotic delivery methods. Until now, SRS services furnished using robotic methods were billed using contractor-priced G-codes G0339 (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment), and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment). We indicated that we would consider deleting these codes in future rulemaking.

Most commenters responded that the CPT codes accurately described both services, and the RUC stated that the direct PE inputs for the CPT codes accurately accounted for the resource costs of the described services. One commenter objected to the deletion of the G-codes but did not include any information to suggest that the CPT codes did not describe the services or that the direct PE inputs for the CPT codes were inaccurate. Based on a review of the comments received, we had no indication that the direct PE inputs included in the CPT codes would not reflect the typical resource inputs involved in furnishing an SRS service. Therefore, in the CY 2014 proposed rule we proposed to recognize only the CPT codes for SRS services, and to delete the G-codes used to report robotic delivery of SRS.

Comment: We received several comments regarding our proposal to delete the SRS G-codes. Some commenters supported our proposal, but most opposed our proposal on the grounds that the direct PE inputs included in the CPT codes do not reflect the typical resource inputs used in furnishing robotic SRS services. Some commenters urged CMS to delay this policy change and continue to contractor price the G-codes until a more appropriate solution can be found.

Response: After consideration of the comments regarding the appropriate inputs to use in pricing the SRS services, we have concluded that at this time, we lack sufficient information to make a determination about the appropriateness of deleting the G-codes and paying for all SRS/SBRT services using the CPT codes. Therefore, we will not delete the G-codes for 2015, but will instead work with stakeholders to identify an alternate approach and reconsider this issue in future rulemaking.

k. Inclusion of Capnograph for Pediatric Polysomnography Services

We proposed to include equipment item EQ358, Sleep capnograph, polysomnography (pediatric), for CPT codes 95782 (Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist) and 95783

(Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist). Based upon our understanding that capnography is a required element of sleep studies for patients younger than 6 years, we proposed to allocate this equipment item to 95782 for 602 minutes, and 95783 for 647 minutes. Based on the invoice we received for this equipment item, we proposed to price EQ358 at $4,534.23.

Comment: We received two comments in support of our proposal to include the capnograph in CPT codes 95782 and 95783.

Response: We appreciate commenters' support for our proposal. After consideration of comments received, we are finalizing our proposal to include the capnograph in CPT codes 95782 and 95783.

4. Using OPPS and ASC Rates in Developing PE RVUs

Accurate and reliable pricing information for both individual items and indirect PEs is critical to establish accurate PE RVUs for PFS services. As we have addressed in previous rulemaking, we have serious concerns regarding the accuracy of some of the information we use in developing PE RVUs. In particular, as discussed in the CY 2014 PFS final rule with comment period, we have several longstanding concerns regarding the accuracy of direct PE inputs, including both items and procedure time assumptions, and prices of individual supplies and equipment (78 FR 74248– 74250). In addition to the concerns regarding the inputs used in valuing particular procedures, we also noted that the allocation of indirect PE is based on information collected several years ago (as described above) and will likely need to be updated in the coming years.

To mitigate the impact of some of these potentially problematic data used in developing values for individual services, in rulemaking for the CY 2014 PFS, 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 and believed OPPS and ASC payment rates would provide an appropriate comparison because these rates are based on relatively more reliable cost information in settings with cost structures that generally would be expected to be higher than in the office setting.

We received many comments regarding our proposal, the vast majority of which urged us to withdraw the proposal. Some commenters questioned the validity of our assumption that facilities' costs for providing all services are necessarily higher than the costs of physician offices or other nonfacility settings. Other commenters expressed serious concerns with the asymmetrical comparisons between PFS payment amounts and OPPS/ASC payment amounts. Finally, many commenters suggested revisions to technical aspects of our proposed policy.

In considering all the comments, however, we were persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that PFS payment rates are based on accurate cost assumptions. Commenters noted several flaws with the approach. First, unlike PFS payments, OPPS and ASC payments for individual services are grouped into rates that reflect the costs of a range of services. Second, commenters suggested that since the ASC rates reflect the OPPS relative weights to determine payment rates under the ASC payment system, and are not based on cost information collected from ASCs, the ASC rates should not be used in the proposed policy. For these and other reasons raised by commenters, we did not propose a similar policy for the CY 2015 PFS. If we consider using OPPS or ASC payment rates in developing

PFS PE RVUs in future rulemaking, we would consider all of the comments received regarding the technical application of the previous proposal.

After thorough consideration of the comments regarding the CY 2014 proposal, we continue to believe that there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated. Although some commenters questioned the premise that the hospital cost data are more accurate than the information used to establish PE RVUs, we continue to believe that the routinely updated, auditable resource cost information submitted contemporaneously by a wide array of providers across the country is a valid reflection of ‘‘relative’’ resources and could be useful to supplement the resource cost information developed under our current methodology based upon a typical case that are developed with information from a small number of representative practitioners for a small percentage of codes in any particular year.

Section 220(a)(1) of the PAMA added a new subparagraph (M) under section 1848(c)(2) of the Act that gives us authority to collect information on resources used to furnish services from eligible professionals (including physicians, non-physician practitioners, PTs, OTs, SLPs and qualified audiologists), and other sources. It also authorizes us to pay eligible professionals for submitting solicited information. We will be exploring ways of collecting better and updated resource data from physician practices, including those that are provider-based, and other non-facility entities paid through the PFS. We believe such efforts will be challenging given the wide variety of practices, and that any effort will likely impose some burden on eligible professionals paid through the PFS regardless of the scope and manner of data collection. Currently, through one of the validation contracts discussed in section II.B. of this final rule with comment period, we have been gathering time data directly from physician practices. Through this project, we

have learned much about the challenges for both CMS and the eligible professionals of collecting data directly from practices. Our own experience has shown that is difficult to obtain invoices for supply and equipment items that we can use in pricing direct PE inputs.

Many specialty societies also have noted the challenges in obtaining recent invoices for medical supplies and equipment (78 FR 74249). Further, PE calculations rely heavily on information from the Physician Practice Expense Information Survey (PPIS) survey, which, as discussed earlier, was conducted in 2007 and 2008. When we implemented the results of the survey, many in the community expressed serious concerns over the accuracy of this or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS.

In addition to data collection, section 1848(c)(2)(M) of the Act as added by section 220(a) of the PAMA provides authority to develop and use alternative approaches to establish PE relative values, including the use of data from other suppliers and providers of services. We are exploring the best approaches for exercising this authority, including with respect to use of hospital outpatient cost data. We understand that many stakeholders will have concerns regarding the possibility of using hospital outpatient cost data in developing PE RVUs under the PFS, and we want to be sure we are aware of these prior to considering or developing any future proposal relying on those data.

Therefore, in the CY 2015 PFS proposed rule (79 FR 40333), we sought comment on the possible uses of the Medicare hospital outpatient cost data (not the APC payment amount) in potential revisions of the PFS PE methodology. This could be as a means to validate or, perhaps, in setting the relative resource cost assumptions within the PFS PE methodology. We noted that the resulting PFS payment amounts would not necessarily conform to OPPS payment amounts since OPPS payments are grouped into APCs, while PFS payments would continue to be valued

individually and would remain subject to the relativity inherent in establishing PE RVUs, budget neutrality adjustments, and PFS updates. We expressed particular interest in comments that compare such possibilities to other broad-based, auditable, mechanisms for data collection, including any we might consider under the authority provided under section 220(a) of the PAMA. We urged commenters to consider a wide range of options for gathering and using the data, including using the data to validate or set resource assumptions for only a subset of PFS services, or as a base amount to be adjusted by code or specialty-level recommended adjustments, or other potential uses. We appreciate the many thoughtful comments that we received on whether and how to use the OPPS cost data in establishing PE relative values. We will consider these as we continue to think about mechanisms to improve the accuracy of PE values.

In addition to soliciting comments as noted above, in the CY 2015 proposed rule we stated that we continue to seek a better understanding regarding the growing trend toward hospital acquisition of physicians' offices and how the subsequent treatment of those locations as off-campus provider-based outpatient departments affects payments under PFS and beneficiary cost-sharing. MedPAC continues to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments, and to recommend that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 *Report to Congress*). We noted that we also remain concerned about the validity of the resource data as more physician practices become provider-based. Our survey data reflects the PE costs for particular PFS specialties, including a proportion of practices that may have become provider-based since the survey was conducted. Additionally, as the proportion of provider-based offices varies among physician specialties, so do the relative accuracy of the PE survey data. Our current PE methodology primarily distinguishes between

the resources involved in furnishing services in two sites of service: The non-facility setting and the facility setting. In principle, when services are furnished in the non-facility setting, the costs associated with furnishing services include all direct and indirect PEs associated with the work and the PE of the service. In contrast, when services are furnished in the facility setting, some costs that would be PEs in the office setting are incurred by the facility. Medicare makes a separate payment to the facility to account for some portion of these costs, and we adjust PEs accordingly under the PFS. As more physician practices become hospital-based, it is difficult to know which PE costs typically are actually incurred by the physician, which are incurred by the hospital, and whether our bifurcated site-of service differential adequately accounts for the typical resource costs given these relationships. We also have discussed this issue as it relates to accurate valuation of visits within the postoperative period of 10- and 90-day global codes in section II.B.4 of this final rule with comment period.

To understand how this trend is affecting Medicare, including the accuracy of payments made through the PFS, we need to develop data to assess the extent to which this shift toward hospital-based physician practices is occurring. To that end, during CY 2014 rulemaking we sought comment regarding the best method for collecting information that would allow us to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments (78 FR 74427). We received many thoughtful comments. However, the commenters did not present a consensus opinion regarding the options we presented in last year's rule. Based on our analysis of the comments, we stated that we believed the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' and hospital services furnished in an off-campus provider-based department of a hospital.

We proposed that the modifier would be reported on both the CMS–1500 claim form for physicians' services and the UB–04 (CMS form 1450) for hospital outpatient claims. (We note that the requirements for a determination that a facility or an organization has provider-based status are specified in §413.65, and we define a hospital campus to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office.)

Therefore, we proposed to collect this information on the type and frequency of services furnished in off-campus provider-based departments in accordance with our authority under section 1848(c)(2)(M) of the Act (as added by section 220(a) of the PAMA) beginning January 1, 2015. The collection of this information would allow us to begin to assess the accuracy of the PE data, including both the service-level direct PE inputs and the specialty-level indirect PE information that we currently use to value PFS services. Furthermore, this information would be critical in order to develop proposed improvements to our PE data or methodology that would appropriately account for the different resource costs among traditional office, facility, and off-campus provider-based settings. We also sought additional comment on whether a code modifier is the best mechanism for collecting this service-level information.

Comment: Many commenters agreed on the need to collect information on the frequency, type, and payment of services furnished in off-campus provider-based departments of hospitals, however, several commenters expressed concern that the HCPCS modifier would create additional administrative burden for providers. Many of these commenters stated that the new modifier would require significant changes to hospitals' billing systems, including a separate charge master for outpatient off-campus PBDs and training for staff on how to use the new modifier. Several commenters thought that education and training would be required for

physician offices to attach a modifier to services furnished in an off-campus provider-based department. These same commenters suggested that a new place of service (POS) code would be more appropriate for physician billing. Several commenters suggested that CMS should re-propose a detailed data collection methodology, test it with providers, make adjustments, and allow additional time for implementation.

Response: While we understand commenters' concerns about the additional administrative burden of reporting a new HCPCS modifier, we have weighed the burden of reporting the modifier for each service against the benefit of having data that will allow us to obtain and assess accurate information on the type and frequency of outpatient hospital services furnished in off-campus provider-based departments, and we do not believe that the modifier is excessively burdensome for providers to report. When billing for hospital services, providers must know where services are furnished in order to accurately complete value code 78 of an outpatient claim or item 32 for service location on the practitioner claim. However, as discussed later in this section, we agree that a POS code on the professional claim allows for the same type of data collection as a modifier and would be less burdensome than the modifier for practitioners. We discuss the timeframe for implementation later in this section.

Comment: Some commenters who were concerned about the administrative burden of the new HCPCS modifier suggested several alternative methods for CMS to collect data on services furnished in off-campus provider-based departments. Several of these commenters recommended that CMS consider establishing of a new POS code for professional claims, or for both professional and hospital claims, because they believed this approach would be less administratively burdensome than attaching a modifier to each service reported on the claim that was furnished in an off-campus provider-based department. Some commenters preferred identifying services furnished in provider-based departments on the Medicare cost report (CMS-

2552-10). Some commenters suggested using provider numbers and addresses to identify off-campus PBDs, or changing the provider enrollment process to be able to track this data. Yet other commenters suggested creating a new bill type to track off-campus PBD services.

Commenters generally recommended that CMS choose the least administratively burdensome approach that would ensure accurate data collection, but did not necessarily agree on what approach would optimally achieve that result. Some commenters believed that a HCPCS modifier would more clearly identify specific services furnished at off-campus PBDs, and would provide better information about the type and level of care furnished. Some commenters believed that a HCPCS modifier would be the least administratively burdensome approach because hospitals and physicians already report a number of claims-based modifiers. However, other commenters stated that additional modifiers would increase administrative burden because this approach would increase the modifiers that would need to be considered when billing.

Response: With respect to creating a new POS code to obtain data on services furnished in off-campus PBDs of a hospital, we note that POS codes are only reported on professional claims and are not included on institutional claims. Therefore, a POS code could not be easily implemented for hospital claims. However, POS codes are already required to be reported on every professional claim, and POS 22 is currently used when physicians' services are furnished in an outpatient hospital department. (More information on existing POS codes is available on the CMS Website at http://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html).

Though we considered proposing a new POS code for professional claims to collect data on services furnished in the off-campus hospital setting, we note that previous GAO and OIG reports (October 2004 A-05-04-0025, January 2005 A-06-04-00046, July 2010 A-01-09-00503 ,

September 2011 A-01-10-00516) have noted frequent inaccuracies in the reporting of POS codes. Additionally, at the time the proposed rule was developed, we had concerns that using a POS code to report this information might not give us the reliable data we are looking to collect, especially if such data were to be cross-walked with hospital claims for the same service, since the hospital claim would have a modifier, not a POS code. However, we have been persuaded by public comments suggesting that use of a POS code on professional claims would be less administratively burdensome than use of a modifier, and would be more familiar to those involved in practitioner billing. Specifically, since a POS code is already required on every professional claim, we believe that creating a new POS code to distinguish outpatient hospital services that are furnished on the hospital campus versus in an off-campus provider-based department would require less staff training and education than would the use of a modifier on the professional claim. Additionally, professional claims only have space for four modifiers; while a very small percentage of professional claims have four modifiers, required use of an additional modifier for every professional claim could lead to more occurrences where there would not be space for all applicable payment modifiers for a specific service. Unlike institutional claims, we note that a new professional claim is required whenever the place of service changes. That is, even if the same practitioner treats the same patient on the same day in the office and the hospital, the services furnished in the office setting must be submitted on one claim with POS 11 (Office), while those furnished in the outpatient hospital department would be submitted on a separate claim with POS 22 (Outpatient Hospital). Likewise, if a new POS code were to be created for off-campus outpatient provider-based hospital department, a separate claim for services furnished in that setting would be required relative to a claim for outpatient services furnished on the hospital's main campus by the same practitioner to the same patient on the same day. Based on public comments and after further consultation with Medicare billing

experts, we believe that use of the POS code on professional claims would be no less accurate than use of a modifier on professional claims in identifying services furnished in off-campus PBDs. In addition, we believe that the POS code would be less administratively burdensome for practitioners billing using the professional claim since a POS code is already required for every professional claim.

With respect to adding new fields to existing claim forms or creating a new bill type, we do not believe that this data collection warrants these measures. We believe that those changes would create greater administrative burden than the proposed HCPCS modifier and POS codes, especially since providers are already accustomed to using modifiers and POS codes. Revisions to the claim form to add new fields or an additional bill type would create significant administrative burden to revise claims processing systems and educate providers that is not necessary given the availability of a modifier and POS codes. Though providers may not be familiar with this new modifier or any new POS code; since these types of codes already exist generally for hospital and professional claims, providers and suppliers should already have an understanding of these types of codes and how to apply them. Finally, we do not believe that expansions to the claim form or use of a new bill type would provide us with detailed information on exactly which services were furnished in an off-campus PBD versus those furnished on the main campus when those services are furnished on the same day.

We also do not believe that we could accurately determine which services are furnished at off-campus provider-base departments (PBDs) using currently available NPI and facility address data. Hospitals are required to report the nine-digit ZIP code indicating where a service was furnished for purposes of paying properly for physician and anesthesia services paid off the PFS when that ZIP code differs from the master address for the hospital on file in CMS claims systems in value code 78 (pub 100-04, transmittal 1681, February 13, 2009). However, the

billing ZIP code for the hospital main campus could be broad enough to incorporate on and off-campus provider-based departments. Further, a ZIP code reported in value code 78 does not allow CMS to distinguish between services furnished in different locations on the same date. Therefore, we do not believe that a comparison of the ZIP code captured in value code 78 and the main campus ZIP code is sufficiently precise.

Finally, while we considered the suggestion that CMS use currently reported Medicare hospital cost report (CMS-2552-10) data to identify services furnished at off-campus PBDs, we note that though aggregate data on services furnished in different settings must be reported through the appropriate cost center, we would not be able to obtain the service-specific level of detail that we would be able to obtain from claims data.

We will take under consideration the suggestion that CMS create a way for hospitals to report their acquisition of physician offices as off-campus PBDs through the enrollment process, although this information, as currently reported, would not allow us to know exactly which services are furnished in off-campus provider based departments and which services are furnished on the hospital's main campus when a hospital provides both on the same day.

Comment: Commenters noted that the proposed modifier would not allow CMS to know the precise location of the off-campus provider-based department for billed services or when services are furnished at different off-campus provider-based locations in the same day.

Response: We agree that neither the proposed modifier nor a POS code provides details on the specific provider-based location for each furnished service. However, we believe that collecting information on the type and frequency of services furnished at all off-campus locations will assist CMS in better understanding the distribution of services between on and off-campus locations.

Comment: MedPAC believed there may be some value in collecting data on services furnished in off-campus provider-based departments to validate the accuracy of site-of-service reporting when the physician's office is off-campus but bills as an outpatient department. MedPAC indicated that any data collection effort should not prevent the development of policies to align payment rates across settings. MedPAC encouraged CMS to seek legislative authority to set equal payment rates across settings for evaluation and management office visits and other select services.

Response: We thank MedPAC for its support of our data collection efforts to learn more about the frequency and types of services that are being furnished in off-campus PBDs.

Comment: Many commenters suggested that providers would not be able to accurately apply the new modifier by the January 1, 2015 implementation timeline and recommended a one-year delay before providers would be required to apply the modifier to services furnished at off-campus PBDs. Some commenters requested only a six-month delay in implementation. Commenters indicated that significant revisions to internal billing processes would require additional time to implement.

Response: Though we believe that the January 1st effective date that applies to most policies adopted in the final rules with comment period for both the PFS and the OPPS would provide sufficient lead time, we understand commenters' concerns with the proposed timeline for implementation given that the new reporting requirements may require changes to billing systems as well as education and training for staff. With respect to the POS code for professional claims, we will request two new POS codes to replace POS code 22 (Hospital Outpatient) through the POS Workgroup and expect that it will take some time for these new codes to be established. Once the revised POS codes are ready and integrated into CMS claims systems, practitioners would be required to use them, as applicable. More information on the

availability of the new POS codes will be forthcoming in subregulatory guidance, but we do not expect the new codes to be available prior to July 1, 2015. There will be no voluntary reporting period of the POS codes for applicable professional claims because each professional claim requires a POS code in order to be accepted by Medicare. However, we do not view this to be problematic because we intend to give prior notice on the POS coding changes and, as many public commenters noted, because practitioners are already accustomed to using a POS on every claim they submit.

We also are finalizing our proposal to create a HCPCs modifier for hospital services furnished in an off-campus PBD setting; but we are adopting a voluntary reporting period for the new HCPCS modifier for one year. That is, reporting the new HCPCS modifier for services furnished at an off-campus PBD will not be mandatory until January 1, 2016, in order to allow providers time to make systems changes, test these changes, and train staff on use of the new modifier before reporting is required. We welcome early reporting of the modifier and believe a full year of preparation should provide hospitals with sufficient time to modify their systems for accurate reporting.

Comment: Many commenters expressed concern that this data collection would eventually lead to equalizing payment for similar services furnished in the non-facility setting and the off-campus PBD setting. Several commenters noted that the trend of hospitals acquiring physician practices is due to efforts to better integrate care delivery, and suggested that CMS weigh the benefits of care integration when deciding payment changes. Some commenters suggested that CMS should use the data to equalize payment for similar services between these two settings. These commenters suggest that there is little difference in costs and care between the two settings that would warrant the difference in payment. Several of these commenters highlighted beneficiary cost sharing as one reason for site-neutral payment, noting that the total

payment amount for hospital outpatient services is generally higher than the total payment amount for those same services when furnished in a physician's office.

Response: We appreciate the comments received. At this time, we are only finalizing a data collection in this final rule with comment period. We did not propose, and therefore, are not finalizing any adjustment to payments furnished in the off-campus PBD setting.

Comment: Several commenters noted that the CMS proposal would not provide additional information on how a physician practice billed prior to becoming an off-campus PBD, which would be important for analyzing the impact of this trend.

Response: We agree that, in analyzing the impact of this trend, it is important to understand physician billing patterns that were in place prior to becoming an off-campus PBD, and we will continue to evaluate ways to analyze claims data to gather this information. We believe that collecting data using the additional modifier and POS code as finalized in this rule will be an important tool in furthering this analysis.

Comment: Some commenters suggested that the term "off-campus" needs to be better defined. Commenters asked how billing would occur for hospitals with multiple campuses since the CMS definition of campus references main buildings and does not include remote locations. One commenter also asked whether the modifier is intended to cover services furnished in free-standing emergency departments.

Response: For purposes of the modifier and the POS codes we are finalizing in this final rule with comment period, we define a "campus" using the definition at §413.65(a)(2) to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus. We agree with commenters that our intent is to

capture data on outpatient services furnished off of the hospital's main campus and off of any of the hospital's other campuses. The term "remote location of a hospital" is defined in our regulations at section 413.65(a)(2). Under the regulation, a "remote location" includes a hospital campus other than the main hospital campus. Specifically, a remote location is "a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purposes of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider…." Therefore, we agree with the commenters that the new HCPCS modifier and the POS code for off-campus PBDs should not be reported for services furnished in remote locations of a hospital. The term "remote location" does not include "satellite" locations of a hospital. However, since a satellite facility is one that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, the new HCPCS modifier and the POS code for off-campus hospital PBDs should not be reported for services furnished in satellite facilities. Satellite facilities are described in our regulations at §412.22(h). Accordingly, reporting of the modifier and the POS code that identifies an off-campus hospital PBD would be required for outpatient services furnished in PBDs that are located beyond 250 yards from the main campus of the hospital, excluding services furnished in a remote location or satellite facility of the hospital.

We also appreciate the comment on emergency departments. We do not intend for hospitals to report the new modifier for services furnished in emergency departments. We note that there is already a POS code for the emergency department, POS 23 (emergency room-hospital), and this would continue to be used on professional claims for services furnished in emergency departments. That is, the new POS code for off-campus hospital PBDs that will be created for purposes of this data collection would not apply to emergency department services.

Hospitals and practitioners that have questions about which departments are considered to be "off-campus PBDs" should review additional guidance that CMS releases on this policy and work with the appropriate CMS regional office if individual, specific questions remain.

Comment: Several commenters asked for clarification on when to report the modifier for services furnished both on and off-campus on the same day. Commenters provided several scenarios of visits and diagnostic services furnished on the same day.

Response: The location where the service is actually furnished would dictate the use of the modifier and the POS codes, regardless of where the order for services is initiated. We expect the modifier and the POS code for off-campus PBDs to be reported in locations in which the hospital expends resources to furnish the service in an off-campus PBD setting. For example, hospitals would not report the modifier for a diagnostic test that is ordered by a practitioner who is located in an off-campus PBD when the service is actually furnished on the main campus of the hospital. This issue does not impact use of the POS codes since practitioners submit a different claim for each POS where they furnish services for a specific beneficiary.

Comment: A few commenters asked for clarification on whether their entity constitutes a provider-based department.

Response: Provider-based departments are departments of the hospital that meet the criteria in §413.65.

Comment: A commenter recommended that CMS publish the data it acquires through adoption of this modifier.

Response: Data collected through the new HCPCS modifier would be part of the Medicare Limited Data Set and would be available to the public for purchase along with the rest of the Limited Data Set. Similarly, professional claims data with revised POS coding would be available as a standard analytic file for purchase.

In summary, after consideration of the comments received, we are finalizing our proposal with modifications. For professional claims, instead of finalizing a HCPCS modifier, in response to comments, we will be deleting current POS code 22 (outpatient hospital department) and establishing two new POS codes— one to identify outpatient services furnished in on-campus, remote or satellite locations of a hospital, and another to identify services furnished in an off-campus hospital PBD setting that is not a remote location of a hospital, a satellite location of a hospital or a hospital emergency department. We will maintain the separate POS code 23 (emergency room-hospital) to identify services furnished in an emergency department of the hospital. These new POS codes will be required to be reported as soon as they become available, however advance notice of the availability of these codes will be shared publicly as soon as practicable.

For hospital claims, we are creating a HCPCS modifier that is to be reported with every code for outpatient hospital services furnished in an off-campus PBD of a hospital. This code will not be required to be reported for remote locations of a hospital defined at §412.65, satellite facilities of a hospital defined at §412.22(h) or for services furnished in an emergency department. This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2015, with the label "PO," the short descriptor "Serv/proc off-campus pbd," and the long descriptor "Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments." Reporting of this new modifier will be voluntary for 1 year (CY 2015), with reporting required beginning on January 1, 2016. Additional instruction and provider education will be forthcoming in subregulatory guidance.

B. Potentially Misvalued Services Under the Physician Fee Schedule

1. Valuing Services Under the PFS

Section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work, PE, and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to mean, "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." In addition, section 1848(c)(2)(C)(i) of the Act specifies that "the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service."

Section 1848(c)(1)(B) of the Act defines the PE component as "the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses." Section 1848(c)(2)(C)(ii) of the Act requires that PE RVUs be determined based upon the relative PE resources involved in furnishing the service. (See section II.A. of this final rule with comment period for more detail on the PE component.)

Section 1848(c)(1)(C) of the Act defines the MP component as "the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service." Section 1848(c)(2)(C)(iii) of the Act specifies that MP expense RVUs shall be determined based on the relative MP expense resources involved in furnishing the service. (See section II.C. of this final rule with comment period for more detail on the MP component.)

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services

a. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of

the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

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

accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress, MedPAC discussed the importance of appropriately valuing physicians' services, noting that "misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services." In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, "When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it." We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made its initial recommendations, "CMS and the RUC have taken several steps to improve the review process." Also, since that time the Congress added section 1848(c)(2)(K)(ii) to the Act, which augments our efforts. It directs the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following seven categories:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;

- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes'); and
- Other codes determined to be appropriate by the Secretary.

Section 220(c) of the Protecting Access to Medicare Act of 2014 (PAMA) further expanded the categories of codes that the Secretary is directed to examine by adding nine additional categories. These are:

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

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section of the Act also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes as authorized by statute over the coming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,250 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

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

In the CY 2014 final rule with comment period, we finalized for review a list of potentially misvalued services. We included on the list for review ultrasound guidance codes that had longer procedure times than the typical procedure with which the code is billed to

Medicare. We also finalized our proposal to replace missing post-operative hospital E/M visit information and work time for approximately 100 global surgery codes. For CY 2014, we also considered a proposal to limit PFS payments for services furnished in a nonfacility setting when the nonfacility PFS payment for a given service exceeds the combined Medicare Part B payment for the same service when it is furnished in a facility (separate payments being made to the practitioner under the PFS and to the facility under the OPPS). Based upon extensive public comment, we did not finalize this proposal. We address our current consideration of the potential use of OPPS data in establishing RVUs for PFS services, as well as comments received, in section II.B. of this final rule with comment period.

c. Validating RVUs of Potentially Misvalued Codes

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

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. We provided a summary of the

comments along with our responses in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (76 FR 73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values used in rate setting, we contracted with the Urban Institute to collect time data from several practices for services selected by the contractor in consultation with CMS. These data will be used to develop time estimates. The Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time. The Urban Institute has prepared an interim report, Development of a Model for the Valuation of Work Relative Value Units, which discusses the challenges encountered in collecting objective time data and offers some thoughts on how these can be overcome. This interim report is available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Urban Interim Report.pdf. Collection of time data under this project has just begun. A final report will be available once the project is complete.

The second contract is with the RAND Corporation, which is using available data to build a validation model to predict work RVUs and the individual components of work RVUs, time, and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND consulted with a technical expert panel on model design issues

and the test results. We anticipate a report from this project by the end of the year and will make the report available on the CMS website.

Descriptions of both projects are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Model.pdf.

We acknowledge comments received regarding the Urban Institute and RAND projects, but note that we did not solicit comments on these projects because we made no proposals related to them. Any changes to payment policies under the PFS that we might make after considering these reports would be issued in a proposed rule and subjected to public comment before they would be finalized and implemented.

3. CY 2015 Identification and Review of Potentially Misvalued Services

a. Public Nomination of Potentially Misvalued Codes

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

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.

- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA NSQIP, STS National Database, and the PQRS databases).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

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

During the comment period to the CY 2014 final rule with comment period, we received nominations and supporting documentation for four codes to be considered as potentially misvalued codes. Although we evaluated the supporting documentation for two of the nominated codes to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued, we did not identify the other two codes until after the publication of the proposed rule. We apologize for this oversight and will address the nomination of CPT codes 92227 and 92228 in the proposed rule for CY 2016.

We proposed CPT code 41530 (submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session) as potentially misvalued based on public nomination due to a significant decrease in two of the direct PE inputs.

Comment: The commenter that nominated this code as potentially misvalued thanked CMS for proposing this code as potentially misvalued, but indicated that the RUC had made recommendations for this code for CY 2015 and further review was no longer necessary. Another commenter suggested that this code should be removed from the list of potentially misvalued codes since it saves Medicare millions of dollars per year.

Response: The RUC only provided us with recommendations for PE inputs for CPT code 41530. Under our usual process, we value work and PE at the same time and would expect to receive RUC recommendations on both before we revalue this service. We disagree with the commenter's statement that codes that may save money for the Medicare program should not be considered as potentially misvalued. Our aim, consistent with our statutory directive, is to value all services appropriately under the PFS to reflect the relative resources involved in furnishing them. After consideration of public comments, we are finalizing CPT code 41530 as potentially misvalued.

We did not propose CPT code 99174 (instrument-based ocular screening (for example, photoscreening, automated-refraction), bilateral) as potentially misvalued, because it is a non-covered service, and we only consider nominations of active codes that are covered by Medicare at the time of the nomination (see 76 FR 73059).

Comment: Commenters did not disagree with CMS not proposing this code as potentially misvalued, but did raise a variety of comments about the code that were unrelated to our proposal.

Response: We continue to believe that our policy to limit the designation of potentially misvalued to those codes that are covered by Medicare is appropriate, so that we focus our limited resources on those services that have an impact on the Medicare program and its beneficiaries. Therefore, we are not including CPT code 99174 on our final list of potentially misvalued codes for CY 2015.

b. Potentially Misvalued Codes

(1) Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More

We proposed 68 codes listed in Table 11 as potentially misvalued codes under the newly established statutory category, "codes that account for the majority of spending under the physician fee schedule." To develop this list, we identified the top 20 codes by specialty (using the specialties used in Table 11) in terms of allowed charges. We excluded those codes that we have reviewed since CY 2009, those codes with fewer than $10 million in allowed charges, and E/M services. E/M services were excluded for the same reason that we excluded them in a similar review for CY 2012. The reason was explained in the CY 2012 final rule with comment period (76 FR 73062 through 73065).

We stated that we believed that a review of the codes in Table 11 is warranted to assess changes in physician work and to update direct PE inputs since these codes have not been reviewed since CY 2009 or earlier. Furthermore, since these codes have significant impact on PFS payment at the specialty level, a review of the relativity of the codes is essential to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties, as discussed previously. For these reasons, we proposed the codes listed in Table 11 as potentially misvalued.

TABLE 11: Potentially Misvalued Codes Identified Through the High Expenditure by Specialty Screen

HCPCS	Short Descriptor
11100	Biopsy skin lesion
11101	Biopsy skin add-on
11730	Removal of nail plate
11750	Removal of nail bed
14060	Tis trnfr e/n/e/l 10 sq cm/
17110	Destruct b9 lesion 1–14
31575	Diagnostic laryngoscopy
31579	Diagnostic laryngoscopy
36215	Place catheter in artery
36475	Endovenous rf 1st vein
36478	Endovenous laser 1st vein
36870	Percut thrombect av fistula
51720	Treatment of bladder lesion
51728	Cystometrogram w/vp
51798	Us urine capacity measure
52000	Cystoscopy
55700	Biopsy of prostate
65855	Laser surgery of eye
66821	After cataract laser surgery
67228	Treatment of retinal lesion
68761	Close tear duct opening
71010	Chest x-ray 1 view frontal
71020	Chest x-ray 2vw frontal&latl
71260	Ct thorax w/dye
73560	X-ray exam of knee 1 or 2
73562	X-ray exam of knee 3
73564	X-ray exam knee 4 or more
74183	Mri abdomen w/o & w/dye
75978	Repair venous blockage
76536	Us exam of head and neck
76700	Us exam abdom complete
76770	Us exam abdo back wall comp
76775	Us exam abdo back wall lim

HCPCS	Short Descriptor
77263	Radiation therapy planning
77334	Radiation treatment aid(s)
78452	Ht muscle image spect mult
88185	Flowcytometry/tc add-on
91110	Gi tract capsule endoscopy
92136	Ophthalmic biometry
92250	Eye exam with photos
92557	Comprehensive hearing test
93280	Pm device progr eval dual
93306	Tte w/doppler complete
93351	Stress tte complete
93978	Vascular study
94010	Breathing capacity test
95004	Percut allergy skin tests
95165	Antigen therapy services
95957	Eeg digital analysis
96101	Psycho testing by psych/phys
96118	Neuropsych tst by psych/phys
96372	Ther/proph/diag inj sc/im
96375	Tx/pro/dx inj new drug addon
96401	Chemo anti-neopl sq/im
96409	Chemo iv push sngl drug
97032	Electrical stimulation
97035	Ultrasound therapy
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/> regions
97530	Therapeutic activities
G0283	Elec stim other than wound

Comment: Many commenters disagreed with the high expenditure screen in principle, stating that the frequency with which a service is furnished (and therefore the total expenditures) is not an indication that the service is misvalued. Specifically, commenters explained that many of the services are highly utilized because of the nature of the Medicare beneficiary population, and not because there is abuse or overutilization. Commenters asserted that the current misvalued code screens can produce a redundant list of potentially misvalued codes while failing to identify codes that are being incorrectly reported. Another commenter urged CMS to work with the RUC to ensure that the code lists identified by the misvalued code screens are accurate. A commenter asked CMS to provide justification for including codes with charges greater than $10 million on the potentially misvalued codes list. Some commenters urged us to reconsider including particular families of codes that were reviewed prior to 2009; others asked that CMS exclude all codes that have been reviewed in the last 10 years; and still others requested that we exclude codes that were bundled several years ago. A commenter stated that the emphasis on codes with spending of more than $10 million demonstrates an agenda to cut spending rather than to ensure appropriate payment, and expressed concern that CMS was simply nominating high value services. Commenters recommended that CMS not finalize its proposed list of potentially misvalued codes, and instead develop a more targeted list of codes that are likely to be misvalued (not just potentially misvalued). Commenters wanted CMS to exempt codes when there have not been fundamental changes in the way the services are furnished or there is no indication that their values are inaccurate, so that specialty societies do not have to go through the work of reviewing them.

Several commenters questioned the statutory authority for CMS's proposal. One commenter questioned CMS's authority under the relevant statute to select potentially misvalued

codes by specialty. The commenter stated that identifying the top 20 codes by specialty in terms of allowed charges does not appear to align with a direct reading of the relevant statutory authority, which allows CMS to identify codes that account for the majority of spending under the PFS, but does not provide for the identification of codes by specialty. The commenter said that a more direct interpretation of the statutory authority would be to select codes based on allowed charges irrespective of specialty, and then to narrow the universe of codes based upon the top codes in terms of allowed charges. Another commenter believed the proposed screen did not comport with the statutory selection criteria because the majority or near majority of spending under the PFS is for evaluation and management (E/M) codes, which CMS excluded from review. The commenter said that if CMS believes that E/M services should not be reviewed - a position the commenter said they would certainly understand- then such a determination is sufficient to meet the statutory mandate to review codes accounting for the majority of PFS spending, and it would then be appropriate for CMS and the RUC to focus efforts on other categories of potentially misvalued codes. The commenter urged CMS at the very least to develop a more targeted list of potentially misvalued services in the category of codes accounting for the majority of PFS spending, and to include codes that are likely to be misvalued, not just potentially misvalued.

Response: Potentially misvalued code screens are intended to identify codes that are possibly misvalued. By definition, these screens do not assert that codes are certainly or even likely misvalued. As we discussed in the CY 2012 PFS final rule with comment period (76 FR 73056), the screens serve to focus our limited resources on categories of codes where there is a high risk of significant payment distortions. One goal is to avoid perpetuating payment for the services at a rate that does not appropriately reflect the relative resources involved in furnishing the service. In implementing this statutory provision, we consider whether the codes

meeting the screening criteria have a significant impact on payment for all PFS services due to the budget neutral nature of the PFS. That is, if codes meeting the screening criteria are indeed misvalued, they would be inappropriately impacting the relative values of all PFS services. Addressing included codes therefore indirectly addresses other codes that do not meet the screening criteria but are themselves misvalued because high expenditure codes are misvalued. We agree with the commenters that high program expenditures and high utilization have varying causes and do not necessarily reflect misvalued codes. However, we continue to believe that the high expenditure screen is nevertheless an appropriate means of focusing our reviews, ensuring appropriate relativity among PFS services, and identifying services that are either over or undervalued. The high expenditure screen is likely to identify misvalued codes, both directly and indirectly.

Regarding screening for codes by specialty, as we discussed above, the included codes have significant impact on PFS payment at the specialty level, therefore a review of the relativity of the codes is essential to ensure that the work and PE RVUs are appropriately relative within the specialty and across specialties. We mentioned in the CY 2012 final rule with comment period how stakeholders have noted that many of the services previously identified under the potentially misvalued codes initiative were concentrated in certain specialties. To develop a robust and representative list of codes for review, we examine the highest PFS expenditure services by specialty and we identify those codes that have not been recently reviewed (76 FR 73060).

Although we understand commenters' concerns that the screens can produce redundant results, we note that we exempted codes that have been reviewed since 2009 for this very reason. We believe that the practice of medicine can change significantly over a 10-year period, and

disagree with commenters' suggestions that no changes would occur over a 10-year period that would significantly affect a procedure's valuation.

Regarding the exclusion of E/M services, we refer the commenters to the extensive discussion in the CY 2012 PFS final rule with comment period (76 FR 73060 through 73065). It is true that E/M services account for significant volume under the PFS, but there are significant issues with reviewing these codes as discussed in the CY 2012 final rule with comment period, and as a result we did not propose to include these codes as potentially misvalued.

Comment: Some commenters suggested other screens that could be used to identify misvalued codes. In addition, even though our proposal only relates to identifying potentially misvalued codes, some commenters commented on our mechanisms for re-valuing misvalued codes.

Response: The only screen for which we made a proposal and sought comments was the high expenditure screen. However, we will consider the suggestions for other screens as we develop proposals in future years. Similarly, our proposal only related to identifying potentially misvalued codes and not how to re-value them if they were finalized as potentially misvalued.

Comment: Several commenters requested that CMS postpone the review of potentially misvalued codes until the revised process we proposed for reviewing new, revised, and potentially misvalued codes is in place.

Response: Although we believe that the revised process for reviewing new, revised, and potentially misvalued codes will improve the transparency of the PFS code review process, we do not believe it is appropriate to postpone the review of all potentially misvalued codes until the new process is implemented. We note that the codes identified in this rule as potentially misvalued would be revalued under the new process, which will be phased in starting for CY 2016 and will apply for all codes revalued for CY 2017.

Comment: Commenters raised several codes that they believed should not be included in the high expenditure screen for a variety of reasons, for example if the code is related to other codes that were recently reviewed and the utilization for the identified service is expected to change significantly as a result of coding changes in the family. Commenters also suggested that codes that have been referred to the CPT Editorial Panel should be excluded from the potentially misvalued codes list.

Response: We acknowledge commenters' suggestion that we exclude particular codes from the screen, but since we are not finalizing a particular list of codes for this screen in this final rule we are not addressing these at this time. We note that we do not agree with commenters that codes that have been referred to CPT by the RUC should be excluded from the potentially misvalued list; rather, we believe that only when these codes are either deleted or revised, and/or we receive new RUC recommendations for re-valuing these codes, would it be appropriate to remove these services from the list.

Comment: A commenter suggested that CMS's high expenditure screen may not account for the fact that many radiology codes have already gone through numerous five-year reviews; have well-established RVUs that are included on the RUC's multispecialty point of comparison (MPC) list; have been included in new, bundled codes; or have PE RVUs that were affected by changes in clinical labor times or equipment utilization assumption changes. The commenter also suggested that the screens do not account for the value that patients receive in terms of better, timelier diagnoses and avoidance of invasive procedures.

Response: We acknowledge that certain types of procedures have been identified through multiple screens; however, we continue to believe that it is appropriate to include most codes that are identified via these screens and not to exclude codes simply because many other procedures furnished by that specialty have already been reviewed. We further note that the

presence of codes on the MPC list makes the case for their review more compelling, given their importance in ensuring overall relativity throughout the PFS. With respect to changes in PE RVUs, we note that cross-cutting policies that affect large numbers of codes are aimed at ensuring overall relativity but do not address the inputs associated with each procedure affected by the change. Finally, a code's status as potentially misvalued does not imply that the service itself is not of inherent value; rather, that its valuation may be inaccurate in either direction.

After considering the comments received, as well as the other proposals we are finalizing, we believe it is appropriate to finalize the high expenditure screen as a tool to identify potentially misvalued codes. However, given the resources required over the next several years to revalue the services with global periods, we believe it is best to concentrate our efforts on these valuations. Therefore, we are not finalizing the codes identified through the high expenditure screen as potentially misvalued at this time. Also, we are not responding to comments at this time regarding whether particular codes should or should not be included in the high expenditure code screen and identified as potentially misvalued codes. We will re-run the high expenditure screen at a future date, and will propose at that time the specific set of codes to be reviewed that meet the high expenditure criteria.

(2) Epidural Injection and Fluoroscopic Guidance – CPT Codes 62310, 62311, 62318, 62319, 77001, 77002 and 77003

For CY 2014, we established interim final rates for four epidural injection procedures, CPT codes 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), 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)), 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) and 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)). These interim final values resulted in CY 2014 payment reductions from the CY 2013 rates for all four procedures.

In the CY 2014 final rule with comment period (78 FR 74340), we described in detail our interim valuation of these codes. We indicated we established interim final work RVUs for these codes that were less than those recommended by the RUC because we did not believe that the RUC-recommended work RVUs accounted for the substantial decrease in time it takes to furnish these services as reflected in the RUC survey data for these four codes. Since the RUC provided no indication that the intensity of the procedures had changed, we indicated that we believed the work RVUs should reflect the reduction in time. We also established interim final direct PE inputs for these four codes based on the RUC-recommended inputs without any refinement. These recommendations included the removal of the radiographic-fluoroscopy room for CPT codes 62310, 62311, and 62318 and a portable C-arm for CPT code 62319.

In response to the comments we received objecting to the CY 2014 interim final values for these codes, we looked at other injection procedures. Other injection procedures, including some that commenters recommended we use to value these epidural injection codes, include the

work and practice expenses of image guidance in the injection code. In the proposed rule, we detailed many of these procedures, which include the image guidance in the injection CPT code. Since our analysis of the Medicare data and comments received on the CY 2014 final rule with comment period indicated that these services are typically furnished with imaging guidance, we believe it would be appropriate for the codes to be bundled and the inputs for image guidance to be included in the valuation of the epidural injection codes as it is for transforaminal and paravertebral codes. We stated that we did not believe the epidural injection codes can be appropriately valued without considering the image guidance, and that bundling image guidance will help assure relativity with other injection codes that include the image guidance. To determine how to appropriately value resources for the combined codes, we indicated that we believed more information is needed. Accordingly, we proposed to include CPT codes 62310, 62311, 62318, and 62319 on the potentially misvalued code list so that we can obtain information to value them with the image guidance included. In the meantime, we proposed to use the CY 2013 input values for CPT codes 62310, 62311, 62318 and 62319 to value these codes for CY 2015. Specifically, we proposed to use the CY 2013 work RVUs and work times.

Because it was clear that inputs that are specifically related to image guidance, such as the radiographic fluoroscopic room, are included in these proposed direct PE inputs for the epidural injection codes, we believed allowing separate reporting of the image guidance codes would overestimate the resources used in furnishing the overall service. To avoid this situation, we also proposed to prohibit the billing of image guidance codes in conjunction with these four epidural injection codes. We stated that we believed our two-tiered proposal to utilize CY 2013 input values for this family while prohibiting separate billing of imaging guidance best ensures that appropriate reimbursements continue to be made for these services, while we gather additional data and input on the best way to value them through codes that include both the

injection and the image guidance.

Comment: The commenters did not object to identifying these codes as potentially misvalued and generally agreed with our proposal to revert to the 2013 inputs for CY 2015.

Response: We appreciate support for our proposal.

Comment: Several commenters agreed that it would be appropriate to bundle the image guidance with the epidural procedures. Other commenters suggested that we create both a bundled code and a stand-alone epidural injection code.

Response: We appreciate commenters' support for our proposal to bundle image guidance with the epidural procedures. As part of the review process, consideration can be given to how to best implement bundled codes.

Comment: Other commenters expressed concern that the bundling approach CMS proposed to use until these codes are reviewed did not incorporate the work or time for fluoroscopy. Some requested that we add the payment for fluoroscopic guidance to the epidural injection codes, as we have done in the past for facet joint injections and other services. Commenters requested that we continue to allow the image guidance codes to be separately billed until these services are revalued. Another commenter suggested that it may be premature to prohibit separate billing for image guidance, as there is considerable variation on the use of fluoroscopic guidance between codes within this family.

Response: We understand commenters' concerns about our proposal to prohibit separate billing for image guidance, and note that these concerns are part of the reason we are referring these codes to the RUC as potentially misvalued. However, given that significant resources are allocated to fluoroscopic guidance within the current injection codes, we do not believe it is appropriate to continue to allow the image guidance to be separately billed while we evaluate these epidural injection codes as potentially misvalued services.

After considering comments received, we are finalizing CPT codes 62310, 62311, 62318, and 62319 as potentially misvalued, finalizing the proposed RVUs for these services, and prohibiting separate billing of image guidance in conjunction with these services.

(3) Neurostimulator Implantation (CPT codes 64553 and 64555)

We proposed CPT codes 64553 (Percutaneous implantation of neurostimulator electrode array; cranial nerve) and 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) as potentially misvalued after stakeholders questioned whether the codes included the appropriate direct PE inputs when furnished in the nonfacility setting.

Comment: A commenter encouraged CMS to include these codes on the potentially misvalued code list to ensure that they are adequately reimbursed in the nonfacility setting, while another commenter disagreed that the work for CPT codes 64553 and 64555 needed to be reviewed.

Response: In general, when a code is proposed as potentially misvalued, unless we receive information that clearly demonstrates it is not potentially misvalued, we finalize the code as potentially misvalued. When we finalize a code as potentially misvalued, we then review the inputs for the code. As a result of such review, inputs can be adjusted either upward or downward.

We appreciate the support for our proposal expressed by some commenters. Since the commenter opposing the addition of these codes to the potentially misvalued code list did not provide justification for its assertion that the work RVUs for CPT codes 64553 and 64555 did not need to be reviewed, after consideration of comments received, we are finalizing CPT codes 64553 and 64555 as potentially misvalued.

(4) Mammography (CPT codes 77055, 77056, and 77057, and HCPCS codes G0202, G0204, and

G0206)

Medicare currently pays for mammography services through both CPT codes, (77055 (mammography; unilateral), 77056 (mammography; bilateral) and 77057 (screening mammography, bilateral (2-view film study of each breast)) and HCPCS G-codes, (G0202 (screening mammography, producing direct digital image, bilateral, all views), G0204 (diagnostic mammography, producing direct digital image, bilateral, all views), and G0206 (diagnostic mammography, producing direct digital image, unilateral, all views)). The CPT codes were designed to be used for mammography regardless of whether film or digital technology is used. However, for Medicare purposes, the HCPCS G-codes were created to describe mammograms using digital technology in response to special payment rules for digital mammography included in the Medicare Benefit Improvements and Protection Act of 2000 (BIPA).

The RUC recommended that CMS update the direct PE inputs for all imaging codes to reflect the migration from film-to-digital storage technologies since digital storage is now typically used in imaging services. Review of the Medicare data with regard to the application of this policy to mammography confirmed that virtually all mammography is now digital. As a result, we proposed that CPT codes 77055, 77056, and 77057 be used to report mammography regardless of whether film or digital technology is used, and to delete the HCPCS G-codes G0202, G0204, and G0206. We proposed to establish values for the CPT codes by crosswalking the values established for the digital mammography G-codes for CY 2015. (See section II.B. of this final rule with comment period for more discussion of this policy.) In addition, since the G-code values have not been evaluated since they were created in CY 2002 we proposed to include CPT codes 77055, 77056, and 77057 on the list of potentially misvalued codes.

Comment: With regard to whether the mammography codes should be included on the

potentially misvalued codes list, commenters had differing opinions. One commenter stated that the work RVUs for digital mammography are the same as those for analog mammography, and maintained that the BIPA-directed payment for digital mammography of 1.5 times the TC of the analog mammography codes appropriately captures the practice expense resources required for digital mammography. Another commenter stated that digital mammography rates resulted from a statutory construct and do not reflect the actual costs of the digital resources necessary to furnish the services. One commenter noted that moving from the non-resource-based values to resource-based values will result in a significant reduction to the valuation of these services, and that this reduction will result from the resource-based PE methodology, not from the RUC review. Another commenter indicated that the RUC should not survey these codes, but requested that if the RUC does survey these codes, they should not do so until after CMS finalizes the new breast tomosynthesis codes (3D mammography) and film-to-digital transition. Another commenter indicated that CMS needed to consider that three-dimensional (3D) mammography codes involve additional resources over the two-dimensional (2D) mammography codes. A commenter suggested that this proposal fails to take into account the increasing use of tomography.

Response: The commenters' disagreement about whether these codes are misvalued would suggest that a review is warranted. Given that more than a decade has passed since these services were reviewed, we continue to believe that it is appropriate to review the work RVUs for these services. By including these codes on the potentially misvalued code list, we will have information to determine whether the current values are still appropriate. Finally, we anticipate that the survey results for the mammography codes will reflect the equipment that is typically used. We note that until these services are reviewed, we do not have adequate information to respond to the suggestion that the valuation for these services will be significantly reduced.

However, we do acknowledge that the PE methodology is not intended to account for the actual costs in furnishing a service; rather, it is required to account for the relative resources in furnishing that service. We also note that there are new CPT codes for reporting mammography using tomosynthesis and we have RUC recommendations for these codes. We believe it is most appropriate to value the mammography code family together, and receipt of RUC recommendations on the other mammography codes will assist us in our review. Accordingly, we are including all mammography codes except those newly created for tomosynthesis on the potentially misvalued code list.

Comment: Although commenters agreed with our assessment that digital technology has replaced analog mammography as typical, not all agreed that it was appropriate to delete G-codes and use the CPT codes. One commenter supported the deletion of the G-codes. Other commenters suggested that deletion of the G-codes was unnecessary. Another commenter stated that the coding system frequently reflects differences in approach and technique, and that the equipment for analog and digital mammography are different enough to warrant separate reporting so we should not delete the G-codes. Some who supported continuation of the G-codes asked us to delay implementation as they were concerned that other payers would not have time to update their requirements by January 1, 2015. Another commenter applauded CMS's decision to delete the G-codes.

Response: In further consideration this proposal, we discovered that while the CPT codes for diagnostic mammography apply to mammography, whether film or digital technology is used, the descriptor for the screening mammography CPT code specifically refers to film. In light of this and that fact that we anticipate revaluing these codes when we have the benefit of RUC recommendations for all codes in the family, we believe it is appropriate to continue to recognize both the CPT codes and the G-codes for mammography for CY 2015, as we consider

appropriate valuations now that digital mammography is typical. Therefore, we are not finalizing our proposal to delete the G-codes. We are, however, making a change in the descriptors to make clear that the G0202, G0204, and G0206 are specific to 2-D mammography. These codes are to be reported with either G0279 or CPT code 77063 when mammography is furnished using 3-D mammography.

Comment: A commenter requested that CMS ensure reimbursement rates remain adequate to protect access for Medicare beneficiaries. Another commenter suggested that these changes could result in barriers to access for Medicare beneficiaries.

Response: We are strongly supportive of access to mammography for Medicare beneficiaries. As stated elsewhere in this final rule with comment period, we believe that accurate valuation incentivizes appropriate utilization of services.

After consideration of public comments, we are modifying our proposal as follows: we will include CPT codes 77055, 77056, and 77057 on the potentially misvalued codes list; we will continue to recognize G0202, G0204 and G0206 but will modify the descriptors so that they are specific to 2-D digital mammography, and instead of using the digital values we will continue to use the CY 2014 work and PE RVUs to value the mammography CPT codes. We expect that the CPT Editorial Panel will consider the descriptor for screening mammography, CPT code 77057, in light of the prevailing use of digital mammography.

(5) Abdominal Aortic Aneurysm Ultrasound Screening (G0389)

When Medicare began paying for abdominal aortic aneurysm (AAA) ultrasound screening, HCPCS code G0389 (Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening) in CY 2007, we set the RVUs at the same level as CPT code 76775 (Ultrasound, retroperitoneal (e.g., renal, aorta, nodes), B-scan and/or real time with image documentation; limited). We noted in the CY 2007 final rule with comment

period that CPT code 76775 was used to report the service when furnished as a diagnostic test and that we believed the service reflected by G0389 used equivalent resources and work intensity to those contained in CPT code 76775 (71 FR 69664 through 69665).

In the CY 2014 proposed rule, we proposed to replace the ultrasound room included as a direct PE input for CPT code 76775 with a portable ultrasound unit based upon a RUC recommendation. Since the RVUs for G0389 were crosswalked from CPT code 76775, the proposed PE RVUs for G0389 in the CY 2014 proposed rule were reduced as a result of this change. However, we did not discuss the applicability of this change to G0389 in the preamble to the proposed rule, and did not receive any comments on G0389 in response to the proposed rule. We finalized the change to CPT code 76775 in the CY 2014 final rule with comment period and as a result, the PE RVUs for G0389 were also reduced.

We proposed G0389 as potentially misvalued in response to a stakeholder suggestion that the reduction in the RVUs for G0389 did not accurately reflect the resources involved in furnishing the service. We sought recommendations from the public and other stakeholders, including the RUC, regarding the appropriate work RVU, time, direct PE input, and malpractice risk factors that reflect the typical resources involved in furnishing the service.

Until we receive the information needed to re-value this service, we proposed to value this code using the same work and PE RVUs we used for CY 2013. We proposed MP RVUs based on the five-year review update process as described in section II.C of this final rule with comment period. We stated that we believe this valuation would ameliorate the effect of the CY 2014 reduction that resulted from the RVUs for G0389 being tied to those for another code while we assess appropriate valuation through our usual methodologies. Accordingly, we proposed a work RVU of 0.58 for G0389 and proposed to assign the 2013 PE RVUs until this procedure is reviewed.

Comment: Many commenters supported our proposal to include this service on the potentially misvalued codes list. Some commenters agreed that the crosswalk used to set rates for this service does not appear to be appropriate at this time, whether due to changes in the way the service is provided, or because the specialty mix has shifted, and suggested that it would be appropriate to establish a Category I CPT code for this service. Another commenter suggested that CMS consider crosswalking G0389 to CPT code 93979 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study). One commenter believed it was unnecessary to survey this code, but recommended that we instead maintain the general ultrasound room as a direct PE input and 2013 PE RVUs.

Response: We appreciate commenters' support for our proposal to include G0389 on the potentially misvalued codes list and are finalizing this proposal. We are finalizing this code as potentially misvalued in large part because we are unsure of the correct valuation. Therefore, we believe it is most appropriate to retain the 2013 inputs until we receive new recommendations, rather than making another change or retaining these inputs indefinitely as commenters suggested.

After consideration of comments received, we are finalizing our proposal to add G0389 to the potentially misvalued codes list, and to maintain the 2013 work and PE RVUs while we complete our review of the code. The MP RVUs will be calculated as discussion in section II.C. of this rule.

(6) Prostate Biopsy Codes – (HCPCS codes G0416, G0417, G0418, and G0419)

For CY 2014, we modified the code descriptors of G0416 through G0419 so that these codes could be used for any method of prostate needle biopsy services, rather than only for prostate saturation biopsies. The CY 2014 descriptions are:

- G0416 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10–20 specimens).
- G0417 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 21–40 specimens).
- G0418 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 41–60 specimens).
- G0419 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; greater than 60 specimens).

Subsequently, we have discussed prostate biopsies with stakeholders, and reviewed medical literature and Medicare claims data in considering how best to code and value prostate biopsy pathology services. After considering these discussions and information, we believed it would be appropriate to use only one code to report prostate biopsy pathology services. Therefore, we proposed to revise the descriptor for G0416 to define the service regardless of the number of specimens, and to delete codes G0417, G0418, and G0419. We believe that using G0416 to report all prostate biopsy pathology services, regardless of the number of specimens, would simplify the coding and mitigate overutilization incentives. Given the infrequency with which G0417, G0418, and G0419 are used, we did not believe that this was a significant change.

Based on our review of medical literature and examination of Medicare claims data, we indicated that we believe that the typical number of specimens evaluated for prostate biopsies is between 10 and 12. Since G0416 currently is used for between 10 and 12 specimens, we proposed to use the existing values for G0416 for CY 2015, since the RVUs for this service were established based on similar assumptions.

In addition, we proposed G0416 as a potentially misvalued code for CY 2015 and sought public comment on the appropriate work RVUs, work time, and direct PE inputs.

Comment: One commenter supported the elimination of the G-codes as a means of simplifying coding requirements, but other commenters opposed our proposal to consolidate the coding into G0416, disagreeing that this would help establish "straightforward coding and maintain accurate payment" as suggested in the proposed rule. Some commenters suggested that we retain the current codes so that biopsy procedures requiring more than 10 specimens can be reimbursed accurately, and indicated that consolidating the coding would further confuse physicians and their staff who have not yet adapted to the CY 2014 coding changes for these G-codes. Other commenters asserted that these changes threaten to undermine access to high quality pathology services. Commenters also stated that the decision to furnish more extensive pathological analysis is not at the discretion of the pathologist, and the pathologist should not be penalized when he or she receives more cores to analyze.

With respect to our proposing G0416 as potentially misvalued, commenters stated that the recent change to these codes has already been confusing and suggests that there is not a clear understanding of what these codes represent, thus making an assessment of their valuation difficult. Commenters further stated that it is unreasonable to consider this a misvalued code when the payment is already 30 percent below what they think it should be, and that CMS has failed to provide justification for why it is potentially misvalued.

The RUC and others suggested that it would be most accurate to utilize CPT code 88305 (Level IV - surgical pathology, gross and microscopic examination) for the reporting of prostate biopsies and to allow the reporting of multiple units. Given the additional granularity and scrutiny given to CPT code 88305 in the CY 2014 final rule, the commenters indicated that they believe that the agency's intent to establish straightforward coding and accurate payment for these services would be realized with this approach.

Response: Given that the typical analysis of prostate biopsy specimens differs significantly from the typical analyses reported using CPT code 88305, as regards the number of blocks used to process the specimen and thus the amount of work involved, we believe that by distinguishing prostate biopsies from other types of biopsies results in more accurate pricing for prostate biopsies. Since CPT code 88305 was revalued with the understanding that prostate biopsies are billed separately, we believe that allowing CPT code 88305 to be reported in multiple units for prostate biopsies would account for significantly more resources than is appropriate. With respect to the concern about higher numbers of specimens, we note that our claims data on the G-codes shows that the vast majority of the claims used G0416, rather than any of the G-codes for greater numbers of specimens.

After consideration of comments received, we are finalizing our proposal to include G0416 on the potentially misvalued codes list, to modify the descriptor to reflect all prostate biopisies, and to maintain the current value until we receive and review information and recommendations from the RUC. We are also finalizing our proposal to delete codes G0417, G0418, and G0419.

(7) Obesity Behavioral Group Counseling – GXXX2 and GXXX3

Pursuant to section 1861(ddd) of the Act, we added coverage for a new preventive benefit, Intensive Behavioral Therapy for Obesity, effective November 29, 2011, and created HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes) for reporting and payment of individual behavioral counseling for obesity. Coverage requirements specific to this service are delineated in the Medicare National Coverage Determinations Manual, Pub. 100–03, Chapter 1, Section 210, available at http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf.

It was brought to our attention that behavioral counseling for obesity is sometimes furnished in group sessions, and questions were raised about whether group sessions could be billed using HCPCS code G0447. To improve payment accuracy, we proposed to create two new HCPCS codes for the reporting and payment of group behavioral counseling for obesity. Specifically, we proposed to create GXXX2 (Face-to-face behavioral counseling for obesity, group (2-4), 30 minutes) and GXXX3 (Face-to-face behavioral counseling for obesity, group (5-10), 30 minutes). We indicated that the coverage requirements for these services would remain in place, as described in the National Coverage Determination for Intensive Behavioral Therapy for Obesity cited above. The practitioner furnishing these services would report the relevant group code for each beneficiary participating in a group therapy session.

Since we believed that the face-to-face behavioral counseling for obesity services described by GXXX2 and GXXX3 would require similar per minute work and intensity as HCPCS code G0447, we proposed work RVUs of 0.23 and 0.10 for HCPCS codes GXXX2 and GXXX3, with work times of 8 minutes and 3 minutes respectively. Since the services described by GXXX2 and GXXX3 would be billed per beneficiary receiving the service, the work RVUs and work time that we proposed for these codes were based upon the assumed typical number of beneficiaries per session, 4 and 9, respectively. Accordingly, we proposed a work RVU of 0.23 with a work time of 8 minutes for GXXX2 and a work RVU of 0.10 with a work time of 3 minutes for GXXX3. We proposed to use the direct PE inputs for GXXX2 and GXXX3 currently included for G0447 prorated to account for the differences in time and number of beneficiaries, and to crosswalk the malpractice risk factor from HCPCS code G0447 to both HCPCS codes GXXX2 and GXXX3, as we believe the same specialty mix will furnish these services. We requested public comment on the proposed values for HCPCS codes GXXX2 and GXXX3.

Comment: Commenters generally supported our proposal to establish a separate payment mechanism for obesity behavioral group counseling services, but raised several concerns regarding the coding structure and valuation of these services. Commenters stated that the work times were inaccurate, requested that the service be valued based on a smaller number of typical group participants, and questioned the need for two G-codes when group counseling services under the PFS are generally billed with a single G-code. A commenter also stated that the lower payment for larger groups will create disincentives for furnishing this service except when there is a full 10-person group, which could limit access. Commenters suggested that CMS only finalize a single G-code for group counseling for intensive behavioral therapy for obesity, and crosswalk the work RVU and work time for this service from the Medical Nutrition Therapy (MNT) group code.

Response: We appreciate commenters' support for our proposal to provide new codes for group obesity counseling services. After reviewing the comments, we agree that it is reasonable to create a single code for group obesity counseling and crosswalk the work RVU and work time from the MNT group code. The individual code for intensive obesity behavioral therapy and the individual MNT code are valued the same, so in the absence of evidence that group composition is different, we believe it makes sense to use the same values. Therefore, we will crosswalk the work RVU of 0.25 and the work time of 10 minutes to a single new G-code for group obesity counseling, G0473 (Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes).

4. Improving the Valuation and Coding of the Global Package

a. Overview

Since the inception of the PFS, we have valued and paid for certain services, such as surgery, as part of global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure (56 FR 59502). For each of these

codes (usually referred to as global surgery codes), we establish a single PFS payment that includes payment for particular services that we assume to be typically furnished during the established global period.

There are three primary categories of global packages that are labeled based on the number of post-operative days included in the global period: 0-day; 10-day; and 90-day. The 0-day global codes include the surgical procedure and the pre-operative and post-operative physicians' services on the day of the procedure, including visits related to the service. The 10-day global codes include these services and, in addition, visits related to the procedure during the 10 days following the procedure. The 90-day global codes include the same services as the 0-day global codes plus the pre-operative services furnished one day prior to the procedure and post-operative services during the 90 days immediately following the day of the procedure.

Section 40.1 of the Claims Processing Manual (Pub. 100–04, Chapter 12 Physician/Nonphysician Practitioners) defines the global surgical package to include the following services when furnished during the global period:

- Preoperative Visits – Preoperative visits after the decision is made to operate beginning with the day before the day of surgery for major procedures and the day of surgery for minor procedures;
- Intra-operative Services – Intra-operative services that are normally a usual and necessary part of a surgical procedure;
- Complications Following Surgery – All additional medical or surgical services required of the surgeon during the postoperative period of the surgery because of complications that do not require additional trips to the operating room;
- Postoperative Visits – Follow-up visits during the postoperative period of the surgery that are related to recovery from the surgery;

- Postsurgical Pain Management – By the surgeon;
- Supplies – Except for those identified as exclusions; and
- Miscellaneous Services – Items such as dressing changes; local incisional care; removal of operative pack; removal of cutaneous sutures and staples, lines, wires, tubes, drains, casts, and splints; insertion, irrigation and removal of urinary catheters, routine peripheral intravenous lines, nasogastric and rectal tubes; and changes and removal of tracheostomy tubes.

b. Concerns with the 10- and 90-Day Global Packages

CMS supports bundled payments as a mechanism to incentivize high-quality, efficient care. Although on the surface, the PFS global codes appear to function as bundled payments similar to those Medicare uses to make single payments for multiple services to hospitals under the inpatient and outpatient prospective payment systems, the practical reality is that these global codes function significantly differently than other bundled payments. First, the global surgical codes were established several decades ago when surgical follow-up care was far more homogenous than today. Today, there is more diversity in the kind of procedures covered by global periods, the settings in which the procedures and the follow-up care are furnished, the health care delivery system and business arrangements used by Medicare practitioners, and the care needs of Medicare beneficiaries. Despite these changes, the basic structures of the global surgery packages are the same as the packages that existed prior to the creation of the resource-based relative value system in 1992. Another significant difference between this and other typical models of bundled payments is that the payment rates for the global surgery packages are not updated regularly based on any reporting of the actual costs of patient care. For example, the hospital inpatient and outpatient prospective payment systems (the IPPS and OPPS, respectively) derive payment rates from hospital cost and charge data reported through annual Medicare

hospital cost reports and the most recent year of claims data available for an inpatient stay or primary outpatient service.

Because payment rates are based on consistently updated data, over time, payment rates adjust to reflect the average resource costs of current practice. Similarly, many of the new demonstration and innovation models track costs and make adjustments to payments. Another significant difference is that payment for the PFS global packages relies on valuing the combined services together. This means that there are no separate PFS values established for the procedures or the follow-up care, making it difficult to estimate the costs of the individual global code component services.

In the following paragraphs, we address a series of concerns regarding the accuracy of payment for 10- and 90- day global codes, including: the fundamental difficulties in establishing appropriate relative values for these packages, the potential inaccuracies in the current information used to price global codes, the limitations on appropriate pricing in the future, the potential for global packages to create unwarranted payment differentials among specialties, the possibility that the current codes are incompatible with current medical practice, and the potential for these codes to present obstacles to the adoption of new payment models.

Concerns such as these commonly arise when developing payment mechanisms, for example fee-for-service payment rates, single payments for multiple services, or payment for episodes of care over a period of time. However, in the case of the post-operative portion of the 10- and 90-day global codes, we believe that together with certain unique aspects of PFS rate setting methodology, these concerns create substantial barriers to accurate valuation of these services relative to other PFS services.

(1) Fundamental Limitations in the Appropriate Valuation of the Global Packages with Post-operative days.

In general, we face many challenges in valuing PFS services as accurately as possible. However, the unique nature of global surgery packages with 10- and 90-day post-operative periods presents additional challenges distinct from those presented in valuing other PFS services. Our valuation methodology for PFS services generally relies on assumptions regarding the resources involved in furnishing the "typical case" for each individual service unlike other payment systems that rely on actual data on the costs of furnishing services. Consistent with this valuation methodology, the RVUs for a global code should reflect the typical number and level of E/M services furnished in connection with the procedure. However, it is much easier to maintain relativity among services that are valued on this basis when each of the services is described by codes of similar unit sizes. In other words, because codes with long post-operative periods include such a large number of services, any variations between the "typical" resource costs used to value the service and the actual resource costs associated with particular services are multiplied. The effects of this problem can be two-fold, skewing the accuracy of both the RVUs for individual global codes and the Medicare payment made to individual practitioners. The RVUs of the individual global service codes are skewed whenever there is any inaccuracy in the assumption of the typical number or kind of services in the post-operative periods. This inaccuracy has a greater impact than inaccuracies in assumptions for non-global codes because it affects a greater number of service units over a period of time than for individually priced services. Furthermore, in contrast to prospective payment systems, such inaccuracies under the PFS are not corrected over time through a ratesetting process that makes year-to-year adjustments based on data on actual costs. For example, if a 90-day global code is valued based on an assumption or survey response that ten post-operative visits is typical, but practitioners reporting the code in fact typically only furnish six visits, then the resource assumptions are overestimated by the value of the four visits multiplied by the number of the times the procedure

code is reported. In contrast, when our assumptions are incorrect about the typical resources involved in furnishing a PFS code that describes a single service, any inaccuracy in the RVUs is limited to the difference between the resource costs assumed for the typical service and the actual resource costs in furnishing one individual service. Such a variation between the assumptions used in calculating payment rates and the actual resource costs could be corrected if the payments for packaged services were updated regularly using data on actual services furnished. Medicare's prospective payment systems have more mechanisms in place than the PFS does to adjust over time for such variation To make adjustments to the RVUs to account for inaccurate assumptions under the current PFS methodology, the global surgery code would need to be identified as potentially misvalued, survey data would have to reflect an accurate account of the number and level of typical post-operative visits, and we (with or without a corresponding recommendation from the RUC or others) would have to implement a change in RVUs based on the change in the number and level of visits to reflect the typical service.

These amplified inaccuracies may also occur whenever Medicare pays an individual practitioner reporting a 10- or 90-day global code. Practitioners may furnish a wide range of post-operative services to individual Medicare beneficiaries, depending on individual patient needs, changes in medical practice, and dynamic business models. Due to the way the 10- and 90-day global codes are constructed, the number and level of services included for purposes of calculating the payment for these services may vary greatly from the number and level of services that are actually furnished in any particular case. In contrast, the variation between the "typical" and the actual resource cost for the practitioner reporting an individually valued PFS service is constrained because the practitioner is only reporting and being paid for a specific service furnished on a particular date.

For most PFS services, any difference between the "typical" case on which RVUs are based and the actual case for a particular service is limited to the variation between the resources assumed to be involved in furnishing the typical case and the actual resources involved in furnishing the single specific service. When the global surgical package includes more or a higher level of E/M services than are actually furnished in the typical post-operative period, the Medicare payment is based on an overestimate of the quantity or kind of services furnished, not merely an overestimation of the resources involved in furnishing an individual service. The converse is true if the RVUs for the global surgical package are based on fewer or a lower level of services than are typically furnished for a particular code.

(2) Questions Regarding Accuracy of Current Assumptions

In previous rulemaking (77 FR 68911 through 68913), we acknowledged evidence suggesting that the values included in the post-operative period for global codes may not reflect the typical number and level of post-operative E/M visits actually furnished.

In 2005, the OIG examined whether global surgical packages are appropriately valued. In its report on eye and ocular surgeries, "National Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005" (A-05-07-00077), the OIG reviewed a sample of 300 eye and ocular surgeries, and counted the actual number of face-to-face services recorded in the patients' medical records to establish whether and, if so, how many post-operative E/M services were furnished by the surgeons. For about two-thirds of the claims sampled by the OIG, surgeons furnished fewer E/M services in the post-operative period than were included in the global surgical package payment for each procedure. A small percentage of the surgeons furnished more E/M services than were included in the global surgical package payment. The OIG identified the number of face-to-face services recorded in the medical record, but did not review the medical necessity of the surgeries or the

related E/M services. The OIG concluded that the RVUs for these global surgical packages are too high because they include a higher number of E/M services than typically are furnished within the global period for the reviewed procedures.

Following that report, the OIG continued to investigate E/M services furnished during global surgical periods. In May 2012, the OIG published a report entitled "Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided" (A-05-09-00053). For this investigation, the OIG sampled 300 musculoskeletal global surgeries and again found that, for the majority of sampled surgeries, physicians furnished fewer E/M services than were included as part of the global period payment for that service. Once again, a small percentage of surgeons furnished more E/M services than were included in the global surgical package payment. The OIG concluded that the RVUs for these global surgical packages are too high because they include a higher number of E/M services than typically are furnished within the global period for the reviewed procedures.

In both reports, the OIG recommended that we adjust the number of E/M services identified with the studied global surgical payments to reflect the number of E/M services that are actually being furnished. However, since it is not necessary under our current global surgery payment policy for a surgeon to report the individual E/M services actually furnished during the global surgical period, we do not have objective data upon which to assess whether the RVUs for global period surgical services reflect the typical number or level of E/M services that are furnished. In the CY 2013 PFS proposed rule (77 FR 44738), we previously sought public comments on collecting these data. As summarized in the CY 2013 PFS final rule (77 FR 68913) we did not discover a consensus among stakeholders regarding either the most appropriate means to gather the data, or the need for, or the appropriateness of using such data in valuing these services. In response to our comment solicitation, some commenters urged us to

accept the RUC survey data as accurate in spite of the OIG reports and other concerns that have been expressed regarding whether the visits included in the global periods reflected the typical case. Others suggested that we should conduct new surveys using the RUC approach or that we should mine hospital data to identify the typical number of visits furnished. Some comments suggested eliminating the 10- and 90-day global codes.

(3) Limitations on Appropriate Future Valuations of 10- and 90-day Global Codes

Historically, our attempts to adjust RVUs for global services based on changes in the typical resource costs (especially with regard to site of service assumptions or changes to the number of post-surgery visits) have been difficult and controversial. At least in part, this is because the relationship between the work RVUs for the 10- and 90-day global codes (which includes the work RVU associated with the procedure itself) and the number of included post-operative visits in the existing values is not always clear. Some services with global periods have been valued by adding the work RVU of the surgical procedure and all pre- and post-operative E/M services included in the global period. However, in other cases, as many stakeholders have noted, the total work RVUs for surgical procedures and post-operative visits in global periods are estimated as a single value without any explicit correlation to the time and intensity values for the individual service components. Although we would welcome more objective information to improve our determination of the "typical" case, we believe that even if we engaged in the collection of better data on the number and level of E/M services typically furnished during the global periods for global surgery services, the valuation of individual codes with post-operative periods would not be straightforward. Furthermore, we believe it would be important to frequently update the data on the number and level of visits furnished during the post-operative periods in order to account for any changes in the patient population, medical practice, or business arrangements. Practitioners paid through the PFS do not report such data.

(4) Unwarranted Payment Disparities

Subsequent to our last comment solicitation regarding the valuation of the post-operative periods (77 FR 68911 through 68913), some stakeholders have raised concerns that global surgery packages contribute to unwarranted payment disparities between practitioners who do and do not furnish these services. These stakeholders have addressed several ways the 10- and 90-day global packages may contribute to unwarranted payment disparities.

The stakeholders noted that, through the global surgery packages, Medicare pays practitioners who furnish E/M services during post-surgery periods regardless of whether the services are actually furnished, while practitioners who do not furnish global procedures with post-operative visits are only paid for E/M services that are actually furnished. In some cases, it is possible that the practitioner furnishing the global surgery procedure may not furnish any post-operative visits. Although we have policies to address the situation when post-operative care is transferred from one practitioner to another, the beneficiary might simply choose to seek care from another practitioner without a formal transfer of care. The other practitioner would then bill Medicare separately for E/M services for which payment was included in the global payment to the original practitioner. Those services would not have been separately billable if furnished by the original practitioner.

These circumstances can lead to unwarranted payment differences, allowing some practitioners to receive payment for fewer services than reflected in the Medicare payment. Practitioners who do not furnish global surgery services bill and are paid only for each individual service furnished. When global surgery values are based on inaccurate assumptions about the typical services furnished in the post-operative periods, these payment disparities can contribute to differences in aggregate RVUs across specialties. Since the RVUs are intended to reflect differences in the relative resource costs involved in furnishing a service, any disparity between

assumed and actual costs results not only in paying some practitioners for some services that are not furnished, it also skews relativity between specialties.

Stakeholders have also pointed out that payment disparities can arise because E/M services reflected in global periods generally include higher PE values than the same services when billed separately. The difference in PE values between separately billed visits and those included in global packages result primarily from two factors that are both inherent in the PFS pricing methodology.

First, there is a different mix of PE inputs (clinical labor/supplies/ equipment) included in the direct PE inputs for a global period E/M service and a separately billed E/M service. For example, the clinical labor inputs for separately reportable E/M codes includes a staff blend listed as "RN/LPN/MTA" (L037D) and priced at $0.37 per minute. Instead of this input, some codes with post-operative visits include the staff type "RN" (L051A) priced at a higher rate of $0.51 per minute. For these codes, the higher resource cost may accurately reflect the typical resource costs associated with those particular visits. However, the different direct PE inputs may drive unwarranted payment disparities among specialties who report global surgery codes with post-operative periods and those that do not. The only way to correct these potential discrepancies under the current system, which result from the specialty-based differences in resource costs, would be to include standard direct PE inputs for these services regardless of whether or not the standard inputs are typical for the specialties furnishing the services.

Second, the indirect PE allocated to the E/M visits included in global surgery codes is higher than that allocated to separately furnished E/M visits. This occurs because the range of specialties furnishing a particular global service is generally not as broad as the range of specialties that report separate individual E/M services. Since the specialty mix for a service is a key factor in determining the allocation of indirect PE to each code, a higher amount of indirect

PE can be allocated to the E/M services that are valued as part of the global surgery codes than to the individual E/M codes. Practitioners who use E/M codes to report visits separately are paid based on PE RVUs that reflect the amount of indirect PE allocated across a wide range of specialties, which has the tendency to lower the amount of indirect PE. For practitioners who are paid for visits primarily through post-operative periods, indirect PE is generally allocated with greater specificity. Two significant steps would be required to alleviate the impact of this disparity. First, we would have to identify the exact mathematical relationship between the work RVU and the number and level of post-operative visits for each global code; and second, we would have to propose a significant alteration of the PE methodology in order to allocate indirect PE that does not correlate to the specialties reporting the code in the Medicare claims data.

Furthermore, stakeholders have pointed out that the PE RVUs for codes with 10- or 90-day post-operative periods reflect the assumption that all outpatient visits occur in the higher-paid non-facility office setting, when many of these visits are likely to be furnished in provider-based departments, which would be paid at the lower, PFS facility rate if they were billable separately. As we note elsewhere in this final rule with comment period, we do not have data on the volume of physicians' services furnished in provider-based departments, but public information suggests that it is not insignificant and that it is growing. When these services are paid as part of a global package, there is no adjustment made based on the site of service. Therefore, even though the PFS payment for services furnished in post-operative global periods might include clinical labor, disposable supply, and medical equipment costs (and additional indirect PE allocation) that are incurred by the facility and not the practitioner reporting the service, the RVUs for global codes reflect all of these costs associated with the visits.

(5) Incompatibility of Current Packages with Current Practice and Unreliability of RVUs for Use in New Payment Models

In addition to these issues, the 10- and 90-day global periods reflect a long-established but no longer exclusive model of post-operative care that assumes the same practitioner who furnishes the procedure typically furnishes the follow-up visits related to that procedure. In many cases, we believe that models of post-operative care are increasingly heterogeneous, particularly given the overall shift of patient care to larger practices or team-based environments.

We believe that RVUs used to establish PFS payments are likely to serve as critical building blocks to developing, testing, and implementing a number of new payment models, including those that focus on bundled payments to practitioners or payments for episodes of care. Therefore, we believe it is critical for us to ensure that the PFS RVUs accurately reflect the resource costs for individual PFS services instead of reflecting potentially skewed assumptions regarding the number of services furnished over a long period of time in the "typical" case. To the extent that the 10- and 90-day global periods reflect inaccurate assumptions regarding resource costs associated with individual PFS services, we believe they are likely to be obstacles to a wide range of potential improvements to PFS payments, including the potential incorporation of payment bundling designed to foster efficiency and quality care for Medicare beneficiaries.

c. Proposed Transformation of 10- and 90-day Global Packages into 0-day Global Packages

Although we have marginally addressed some of the concerns noted above with global packages in previous rulemaking, we do not believe that we have made significant progress in addressing the fundamental issues with the 10- and 90-day post-operative global packages. In the context of the misvalued code initiative, we believe it is critical for the RVUs used to develop PFS payment rates reflect the most accurate resource costs associated with PFS services. Based on the issues discussed above, we do not believe we can effectively address the issues inherent in establishing values for the 10- and 90-day global packages under our existing methodologies and

with available data. As such, we do not believe that maintaining the post-operative 10-and 90-day global periods is compatible with our continued interest in using more objective data in the valuation of PFS services and accurately valuing services relative to each other. Because the typical number and level of post-operative visits during global periods may vary greatly across Medicare practitioners and beneficiaries, we believe that continued valuation and payment of these face-to-face services as a multi-day package may 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, whether through the current PFS or in any number of new payment models. 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.

To address the issues discussed above, we proposed to retain global bundles for surgical services, but to refine bundles by transforming over several years all 10- and 90-day global codes to 0-day global codes. Medically reasonable and necessary visits would be billed separately during the pre- and post-operative periods outside of the day of the surgical procedure. We propose to make this transition for current 10-day global codes in CY 2017 and for the current 90-day global codes in CY 2018, pending the availability of data on which to base updated values for the global codes.

We believe that transforming all 10- and 90-day global codes to 0-day global codes would:

- Increase the accuracy of PFS payment by setting payment rates for individual services based more closely upon the typical resources used in furnishing the procedures;

- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global; and
- Facilitate availability of more accurate data for new payment models and quality research.

As we transition these codes, we would need to establish RVUs that reflect the change in the global period for all the codes currently valued as 10- and 90-day global surgery services. We sought assistance from stakeholders on various aspects of this task. Prior to implementing these changes, we intend to gather objective data on the number of E/M and other services furnished during the current post-operative periods and use those data to inform both the valuation of particular services and the overall budget neutrality adjustments required to implement this proposal. We sought comment on the most efficient means of acquiring accurate data regarding the number of visits and other services actually being furnished by the practitioner during the current post-operative periods. For all the reasons stated above, we do not believe that survey data reflecting assumptions of the "typical case" meets the standards required to measure the resource costs of the wide range of services furnished during the post-operative periods. We acknowledge that collecting information on these services through claims submission may be the best approach, and we would propose such a collection through future rulemaking. However, we are also interested in alternatives. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services furnished during the post-operative period, and how we might collect and objectively evaluate that data.

We also sought comment on the best means to ensure that allowing separate payment of E/M visits during post-operative periods does not incentivize otherwise unnecessary office visits during post-operative periods. If we adopt this proposal, we intend to monitor any changes in the utilization of E/M visits following its implementation but we also solicited comment on potential payment policies that will mitigate such a change in behavior.

In developing this proposal, we considered several alternatives to the transformation of all global codes to 0-day global codes. First, we again considered the possibility of gathering data and using the data to revalue the 10- and 90- day global codes. While this option would have maintained the status quo in terms of reporting services, it would have required much of the same effort as this proposal without alleviating many of the problems associated with the 10- and 90-day global periods. For example, collecting accurate data would allow for more accurate estimates of the number and kind of visits included in the post-operative periods at the time of the survey. However, this alternative approach would only mitigate part of the potential for unwarranted payment disparities. For example, the values for the visits in the global codes would continue to include different amounts of PE RVUs than separately reportable visits and would continue to provide incentives to some practitioners to minimize patient visits. Additionally, it would not address the changes in practice patterns that we believe have been occurring whereby the physician furnishing the procedure is not necessarily the same physician providing the post-procedure follow up.

This alternative option would also rest extensively on the effectiveness of using the new data to revalue the codes accurately. Given the unclear relationship between the assigned work RVUs and the post-operative visits across all of these services, incorporating objective data on the number of visits to adjust work RVUs would still necessitate extensive review of individual codes or families of codes by CMS and stakeholders, including the RUC. We believe the

investment of resources for such an effort would be better made to solve a broader range of problems.

We also considered other possibilities, such as altering our PE methodology to ensure that the PE inputs and indirect PE for visits in the global period were valued the same as separately reportable E/M codes or requiring reporting of the visits for all 10- and 90-day global services while maintaining the 10- and 90-day global period payment rates. However, we believe this option would require all of the same effort by practitioners, CMS, and other stakeholders without alleviating most of the problems addressed in the preceding paragraphs.

We also considered maintaining the status quo and identifying each of the 10- and 90-day global codes as potentially misvalued through our potentially misvalued code process for review as 10- and 90-day globals. Inappropriate valuations of these services has a major effect on the fee schedule due to the percentage of PFS dollars paid through 10- and 90-day global codes (3 percent and 11 percent, respectively), and thus, valuing them appropriately is critical to appropriate valuation and relativity throughout the PFS. Through the individual review approach, we could review the appropriateness of the global period and the accurate number of visits for each service. Yet revaluing all 3,000 global surgery codes through the potentially misvalued codes approach would not address many of the problems identified above. Unless such an effort was combined with changes in the PE methodology, it would only partially address the valuation and accuracy issues and would leave all the other issues unresolved. Moreover, the valuation and accuracy issues that could be addressed through this approach would rapidly be out of date as medical practice continues to change. Therefore, such an approach would be only partially effective and would impede our ability to address other potentially misvalued codes.

We sought stakeholder input on an accurate and efficient means to revalue or adjust the work RVUs for the current 10- and 90-day global codes to reflect the typical resources involved in furnishing the services including both the pre- and post-operative care on the day of the procedure. We believe that collecting data on the number and level of post-operative visits furnished by the practitioner reporting current 10-and 90-day global codes will be important to ensuring work RVU relativity across these services. We also believe that these data will be important to determine the relationship between current work RVUs and current number of post-operative visits, within categories of codes and code families. However, we believe that once we collect those data, there is a wide range of possible approaches to the revaluation of the large number of individual global services, some of which may deviate from current processes like those undertaken by the RUC. To date, the potentially misvalued code initiative has focused on several hundred, generally high-volume codes per year. This proposal requires revaluing a larger number of codes over a shorter period of time and includes many services with relatively low volume in the Medicare population. Given these circumstances, it does not seem practical to survey time and intensity information on each of these procedures. Absent any new survey data regarding the procedures themselves, we believe that data regarding the number and level of post-service office visits can be used in conjunction with other methods of valuation, such as:

- Using the current potentially misvalued code process to identify and value the relatively small number of codes that represent the majority of the volume of services that are currently reported with codes with post-operative periods, and then adjusting the aggregate RVUs to account for the number of visits and using magnitude estimation to value the remaining services in the family.

- Valuing one code within a family through the current valuation process and then using magnitude estimation to value the remaining services in the family.

- Surveying a sample of codes across all procedures to create an index that could be used to value the remaining codes.

Although we believe these are plausible options for the revaluation of these services, we believed there may be others. Therefore, we sought input on the best approach to achieve this proposed transition from 10- and 90-day, to 0-day global periods, including the timing of the changes, the means for revaluation, and the most effective and least burdensome means to collect objective, representative data regarding the actual number of visits currently furnished in the post-operative global periods. We also solicited comment on whether the effective date for the transition to 0-day global periods should be staggered across families of codes or other categories. For example, while we proposed to transition 10-day global periods in 2017 and 90-day global periods in 2018, we solicited comment on whether we should consider implementing the transition more or less quickly and over one or several years. We also solicited comment regarding the appropriate valuation of new, revised, or potentially misvalued 10- or 90-day global codes before implementation of this proposal.

We received many comments regarding the proposed transition to 0-day global packages. Many commenters expressed support or opposition to the proposal. Some commenters offered direct responses to the topics for which we specifically sought comment, while others raised questions regarding how the transition would be implemented. In the following paragraphs, we summarize and respond to these comments.

Comment: Several commenters supported the proposal, including commenters representing several medical specialty societies and several health systems. Many of these commenters agreed with the reasons presented in the proposal. These commenters agreed that the current structure of the global surgery codes prevents CMS from accurately valuing and paying for these services, even if CMS had necessary visit data available. Many commenters

agreed that the current arrangement may lead to unwarranted payment disparities and that the current packages have not evolved with changes in practice and because of this, likely provide unreliable building blocks for new payment methodologies.

In agreeing with the proposal, MedPAC stated that it "is essential that the individual services that make up a bundle have accurate values and that there is a mechanism to ensure that the services that are part of the bundle are not paid separately (unbundling). Otherwise, the payment rate for the entire bundle will be inaccurate." MedPAC urged CMS to finalize this proposal and plan to use the more accurate valuations to create more accurate bundles in the future.

Response: We appreciate the commenters' support for the proposal, and agree that there are many reasons why the current construction of the global surgery packages is difficult to reconcile with accurate valuation of individual services within the current payment construct of the PFS. We agree that achieving the agency's goal of greater bundling requires accurate valuation of component services in a surgical procedure.

Comment: Some commenters, including several of those representing specialty societies, urged CMS to postpone finalization of the proposal pending the report of stakeholder efforts to conduct a comprehensive analysis of the effect it would have on the provision of surgical care, surgical patients, and the surgeons who care for them.

Response: We share stakeholders' concerns regarding the potential impact of the change on Medicare beneficiaries and practitioners. However, based upon our analysis and the information that stakeholders have provided, we believe delaying the proposal to further study the problems is not warranted given the significant concerns that have been raised with the current construction of the global surgery packages . Instead, as we articulated in making the proposal, we anticipate that further analysis by stakeholders will contribute to implementing the

transition in a manner that accurately values and pays for PFS services. We believe that accurate valuation of services furnished to Medicare beneficiaries is overwhelmingly in the best interest of both beneficiaries and those who care for them.

Comment: We received several comments from commenters who opposed our proposal, and in general these commenters shared the concerns of those who urged a delay in finalizing or implementing the proposal. In addition, some commenters who opposed the proposal disputed our contention that the global periods contribute to unwarranted payment disparities, saying that the increased direct and indirect PE and MP RVUs for E/M services furnished in the global surgical post-operative periods accurately account for the increased PE and MP costs of practitioners who furnish these services relative to practitioners who typically furnish separately reportable E/M services.

Response: Just as we do not agree that we should delay addressing significant problems with valuations while we further study the issues, we do not believe these same issues raised by commenters opposing the proposal are impediments to implementation. The issues relating to valuation of global period E/M services using our PE methodology are just one of several important considerations that led us to propose transforming 10- and 90-day global services to 0-day global packages. We continue to believe the proposed transformation to 0-day global packages is a simple and immediate step to improve the valuation of the various services included in surgical care. However, Medicare remains committed to bundled payment as a mechanism for delivery system reform and we will continue to explore the best way to bundle surgical services, including alternatives to the 0-day global surgical bundle.

Comment: Many commenters who opposed the proposal addressed valuation problems that would exist if the proposal were implemented. Some stated that, were CMS to finalize the proposal to pay for post-surgical E/Ms using the same codes, the PE and MP RVUs for the

services would be artificially reduced because the data from other specialties would be incorporated. These commenters suggested CMS should consider how to maintain the current differences in payment for these services even if the proposal were finalized. Some commenters suggested that CMS would need to account for the additional practice expense and malpractice costs for post-operative surgical visits.

Response: We develop and establish work, PE, and MP RVUs for specific services to reflect the relative resource costs involved in furnishing the typical PFS service. In developing the proposal, we noted that by including a significant number of E/Ms in the global periods for surgical services, the PFS ratesetting methodology distinguishes these services from other E/Ms for purposes of developing PE and MP RVUs, potentially to the advantage of particular specialties with higher PE and MP RVUs. In contrast, the work RVUs for individual, separately billed E/M services furnished, for example, by primary care practitioners are valued more generally as individual services, and values are not maintained separately from the work RVUs for E/Ms furnished by other practitioners. Therefore, we do not agree with commenters that Medicare should establish higher PE and MP values for E/M services furnished in the post-surgical period than for other E/M services.

Comment: Several commenters suggested that CMS should not use the OIG reports to generalize its concerns about the provision of surgical care, because the OIG reports represent only a small sample of observations of specific procedures and specialties. Other commenters suggested that the OIG methodology might be flawed because, since CMS does not require documentation of post-operative visits, many practitioners may not document such visits in the medical record.

Response: We do not have any reason to believe that the OIG findings on the global surgical service packages furnished by particular specialties that the OIG reviewed are not

generalizable to other global surgery services. Nor did the commenters provide any evidence that the OIG conclusions are likely to be less accurate than the survey estimates that CMS uses to value the services. Finally, having an incorrect number of postoperative visits is only one of the many valuation problems that have been identified for global surgical packages. Additionally, we find the suggestion that physicians do not document medical visits that are occurring in the post-surgical period to be concerning. As a general matter, Medicare does not require documentation to support a billed service beyond information that the physician would normally maintain in the patient's medical record. Even in the absence of billing Medicare or another insurer, we believe that physicians and other practitioners following standard medical practice would document what occurred during a patient encounter in order to ensure the patient's medical history is accurate and up-to-date, and to facilitate continuity in the patient's medical care.

Comment: One commenter asserted that the 90-day global period was created to prevent two behaviors referred to as "fee-splitting" and "itinerant surgery." According to the commenter, these terms refer to the practice where a surgeon would provide only the surgery and leave postoperative care to other practitioners. The commenter believes these practices are inconsistent with professional standards, and that it is medically necessary and expected by patients that surgeons will evaluate their patients on a daily basis in the hospital and as needed on an outpatient basis during the recovery period.

Response: We do not believe that the global surgical package was designed to ensure or allocate appropriate post-operative care among practitioners. Under Medicare's current global surgery policy, practitioners can agree on the transfer of care during the global period and, in such cases, modifiers are used in order to split the payment between the procedure and the post-operative care. We do not agree that global surgical packages obligate the surgeon to furnish

some or all of the post-operative care. Global surgical packages are valued based on the typical service, and we would not expect every surgery to require the same number of follow-up visits. However, we would expect that over a large number of services, the central tendency would reflect the number of visits we included as typical for purposes of valuing the global package; and as discussed above, we have not found that this is necessarily the case. . Even if Medicare maintains the 10- and 90-day global surgery packages, there would be no assurance that the surgeon, and not another practitioner, would furnish all or a certain amount of post-operative care (whether by the patient's choice of practitioner or otherwise). The global payment includes payment for post-operative care with the payment for the surgery, which makes it difficult to know whether or by whom the post-operative care was actually furnished unless there is an official transfer of care. We are confident that the surgical community will continue to furnish appropriate care for Medicare beneficiaries irrespective of changes in the structure of payment for surgical services.

Comment: Several commenters stated that if Medicare adopts a policy to pay for post-operative care using E/M codes rather than through a global package, Medicare will likely pay a higher level of E/M visits when they are separately billed than it does currently, as the existing global packages tend to include more lower level E/M services than those that are generally reported.

Response: We acknowledge that the visits assumed in the global packages are generally valued as lower-level visits than are most commonly furnished, as reflected in Medicare utilization data for separately reportable E/Ms. However, this disparity is only pertinent to the proposal if the global packages are inaccurately valued or, if, under the proposed policy, practitioners who furnish these services are likely to inaccurately report the level of E/M service that is actually being furnished. If the former is true, then we believe this supports the proposal to

revalue these services. As with every service, we expect physicians to bill the most appropriate E/M codes that reflect the care that is furnished, including for post-operative care.

Comment: One commenter expressed concern that the proposal to require separate billing for postoperative surgical care provides a basis for the eventual denial of payment to one or more of the postoperative care providers, based on the notion that care furnished by other specialties is duplicative of or replaces care furnished by the surgeon. This commenter stated that multiple providers with differing expertise and training are essential to achieve optimal patient outcomes and expressed concern that this proposal will provide disincentives to optimal patient care.

Response: As we stated in the proposal, we believe that there are various models for postoperative care that can often include multiple providers, and this is another important reason why we believe the services with longer global periods should be transformed to 0-day packages to accommodate heterogeneous models of care that optimize patient outcomes.

Comment: One commenter recommended that CMS establish G-codes for three levels of post-operative visits furnished by the original surgeon or another surgeon with the same board certification, as well as a second set of three level G-codes for postoperative visits furnished by another provider. The commenter also suggested that CMS should develop methods to fairly measure the duration of E/M times through which a large sample of surgeons might report the number and intensity of post-operative visits. The commenter also recommended that CMS track E/M services furnished to surgical patients within the global period by a physician other than the operating surgeon, for the same or similar diagnosis, in order to begin to understand what portion of postoperative visits are being billed outside of the global period.

The RUC informed CMS that it has identified several large hospital-based physician group practices that internally use CPT code 99024 to report each bundled post-operative visit,

and therefore data is already being captured for some Medicare providers. The RUC also suggested that CMS may have denied-claims data available for CPT code 99024 via the Medicare claims processing system. The RUC recommends that CMS work with it to explore the availability, usefulness, and appropriateness of these data from group practices and the CMS denied-claims dataset, in order to gather existing, objective data to validate the actual number of post-operative visits for 10-day and 90-day procedures. The RUC also suggested that CMS should consider reviewing Medicare Part A claims data to determine the length of stay for surgical services furnished in the inpatient acute care hospital setting.

MedPAC stated that data collection could take several years, would be burdensome for CMS and providers, and may be inaccurate since providers would have little incentive to report each visit. Furthermore, MedPAC suggested that such data collection would be unnecessary since the current ratesetting methodology already assumes particular numbers of visits. MedPAC suggested that CMS should reduce the RVUs for the 10- and 90-day global services based on the same assumptions currently used to pay for these services.

Several other commenters agreed with the approach advocated by MedPAC (often referred to as "reverse-building block") to revaluing the services. These commenters stated that since CMS has increased RVUs for these services proportionate to the number of E/M services assumed to be included in the postoperative period, for the sake of relativity, the RVUs attributed to the visits can be fairly removed in order to value the new 0-day global codes. Many of these commenters acknowledged that this approach would result in negative or other anomalous values for many of these codes, but asserted that codes with anomalous values might then be individually reviewed. MedPAC suggested that if specialty societies or the RUC believe that the new values for specific global codes are inaccurate, they could present evidence that the codes are misvalued to CMS, presumably through the potentially misvalued code public

nomination process. MedPAC further states that for codes without accurate post-operative assumptions, CMS could calculate interim RVUs for these codes based on the average percent reduction for other global codes in the same family.

Many other commenters were against the reverse-building block approach to revaluation. These commenters stated that backing out the bundled E/M services would be highly inappropriate and methodologically unsound since the services were not necessarily valued using a building-block methodology. Many of these commenters, including the RUC, stated that the amount of post-operative work included in the codes can only be appropriately surveyed, vetted, and valued by the RUC.

Response: We appreciate the concerns of commenters regarding the difficulty of revaluing the global surgery codes as 0-day global packages. As we stated in making the proposal, we believe that such stakeholder input and participation in any revaluation will be critical to the accuracy of the resulting values. We will consider all of these comments as we consider mechanisms for revaluations and as we propose new values for specific services. We believe that the challenges involved in revaluation, such as those articulated by commenters, reinforce our understanding that the current construction of the 10- and 90-day global packages are not a sustainable, long-term approach to the accurate valuation of surgical care. . As noted above, we will continue to explore appropriate ways of bundling global surgical services.

Comment: In general, commenters supporting the proposal also supported CMS's proposed timeframe to transition 10-day global codes and 90-day global codes to 0-day global surgical packages by 2017 and 2018, respectively. In contrast, most commenters objecting to, or articulating reservations about, the proposal urged CMS to slow its implementation. Some of these commenters suggested that the process used to establish the current values for these CPT

codes is ideal and stated that it would take many years to value the many individual services using the same methodologies.

The RUC stated that there are over 4,200 services within the PFS with a 10-day or 90-day global period, so the scope of the proposal is very large and the transition should be staggered over many years. However, the RUC also pointed out that most of these services have relatively low utilization, as only 268 of them (or 6 percent of 10- or 90-day global surgery services) were performed more than 10,000 times annually based on 2013 Medicare claims data.

Response: We appreciate the concerns of the commenters. We agree with those commenters who urged us to move quickly to value services as accurately as possible. We note that most comments suggesting a delay in revaluation were based on a common underlying view that code-level review of the full set of services by the RUC based on practitioner surveys is the only appropriate way to value the services.

As we stated in making the proposal, we do not believe that surveying practitioners who furnish each of these services is a practical or necessarily advisable approach to appropriate valuation. Regardless of when the proposal is implemented, it seems likely that the number of codes to be revalued is much larger than the number of codes that should or can be surveyed. Through its normal process, the RUC routinely makes annual recommendations regarding several hundred codes, and we acknowledge that thousands of services cannot be valued using the typical RUC process in one year. On the other hand we believe that there are other options for revaluing some of the global surgery codes as 0-day global packages, particularly those of low volume, and we have indicated a willingness to work with the RUC to determine appropriate mechanisms for revaluations. Therefore, although we agree that revaluing such a high number of codes is a significant undertaking, we do not believe that that the required revaluations would represent an undue burden between the present and the proposed implementation dates. We also

note that in order to focus efforts on revaluing the global surgery packages, we are not asking the RUC to review the nearly 100 services we proposed as potentially misvalued this year under the high expenditure screen. We continue to remain interested in other potential data sources for accurately valuing PFS services, especially the vast majority of 10- and 90-day global codes for which there is not significant volume. We also urge stakeholders to engage with us to help us understand why alternative approaches to the revaluation of the 10- and 90-day global services would require the kind of delay that was urged based on the assumption that the RUC survey approach would be used for all those services.

Additionally, we request stakeholders, including the CPT Editorial Panel and the RUC, to consider the utility of establishing and maintaining separate coding and national Medicare RVUs for the many procedures that have little to no utilization in the Medicare population. For example, there are over 1,000 10- and 90-day global codes with fewer than 100 annual services in the Medicare database. Although we recognize that some portion of these services may be utilized more extensively by non-Medicare payers, it is also likely that many of these codes may reasonably be consolidated. We request that appropriate coding for surgical services be considered as part of revaluing global surgery.

Comment: Many commenters expressed concerns that requiring beneficiary coinsurance for each follow-up visit could dissuade beneficiaries from returning for necessary follow-up care and, therefore, adversely affect surgical outcomes. Many of these commenters acknowledged that overall patient liability for the total amount of care could be reduced, depending on revaluation, but stated that paying separate coinsurance for follow-up care can cause patients to perceive the net payments as larger, given the frequency of payment required. These commenters stated that the magnitude of these problems might be directly proportionate to how sick the patient is.

Response: We understand the concerns of the commenters, but do not agree that Medicare beneficiaries are unlikely to appreciate the difference between frequency of payment and overall financial liability. We also note that the significant majority of patient encounters with Medicare practitioners generate some degree of beneficiary liability. While liability could prompt the proportion of beneficiaries without secondary insurance to forgo medically reasonable and necessary care for the treatment of illness or injury, we have no reason to conclude that this would be the case specifically for post-operative care. We do acknowledge that surgeons may need to explain the importance of follow-up care so that patients understand and appreciate how compliance with follow-up care can improve the overall quality of care and outcomes. As noted above, while our proposal is to move to 0-day global packages as a simple, immediate adjustment, the agency remains committed to bundling as a key component of payment system delivery reform, and we will consider beneficiary impact as we further consider the appropriate size and construction of a surgical bundle.

Comment: Several commenters expressed concerns that the proposal would result in disjointed or inadequate care and/or disrupt surgical registry data. These commenters suggested that neither patients nor alternate providers are as qualified to determine whether or not a postoperative visit by the surgeon is necessary.

Response: As discussed above, we do not agree that patients who require the post-operative care of a surgeon are likely to forgo such care if Medicare changes how we pay the surgeon for furnishing that care. Although several commenters expressed these and similar kinds of concerns, none explained how the proposed change in payment would change post operative care. We continue to believe that surgeons will continue to furnish appropriate post operative care to Medicare beneficiaries, and we do not agree that concerns about increased patient liability or disjointed care are warranted.

Comment: Several commenters expressed concerns over other Medicare payment policies related to surgical procedures. Some commenters stated that the current multiple procedure payment reduction policies that apply to all 0-, 10-, and 90-day global codes are only appropriate for 10-day and 90-day globals due to the overlap in resource costs during the post-operative period. Other commenters noted that potential reductions in payment to surgeons to account for the reduced post-operative period would negatively impact practitioners who assist at surgery despite the fact that their professional work and responsibilities have not changed.

Response: We appreciate the issues raised by these commenters. Again, we seek continued input from the stakeholder community regarding these and other issues that need to be considered in order to implement the transition. In the case of the MPPR, we note there are several hundred 0-day global codes where these payment policies currently apply. We are especially interested in understanding why stakeholders do not believe the policies effective for the current 0-day global codes would not similarly be appropriate for the current 10-and 90-day codes that will be revalued as 0-day global codes.

Comment: Many of the commenters who opposed or expressed concern about the proposal urged CMS to consider the extent to which this proposal would increase the administrative burden on CMS, MACs, and providers. Other commenters urged CMS to consider that post-operative visits would be subject to the same documentation requirements and other scrutiny as other separately-reportable PFS services. One commenter representing other payers opposed the proposal due to concerns about predicting the usage of post-operative services.

Response: We considered the administrative burden on both CMS and practitioners who furnish these services in making the proposal. In both cases, we note the administrative burden would be no greater than the burden associated with the vast majority of other services paid

through the Medicare PFS. We do not believe that the burden of separately reporting post-operative follow-up visits is particularly or unduly burdensome, given that most office visits paid through the PFS are separately reported under current Medicare policies. In comparison to the number of separately reported visits and other PFS services, the number of visits that likely occur in post-operative periods is relatively small. We do not agree that there are inherent reasons that medically necessary post-operative visits should be exempt from the same documentation and other requirements applicable to other PFS services. We appreciate that changes in Medicare policy may affect other insurers who choose to base their payments on the PFS; however, it is our obligation to set our policies based upon the needs of Medicare and its beneficiaries.

Comment: A few commenters urged CMS to consider the possibility that there could be confusion among practitioners and payers if some payers continue to base payment on the 10- or 90-day post-operative periods.

Response: We believe that payment policies that are appropriate for Medicare may not always be optimal for all payers. However, we seek continued input and analysis from other payers as we engage stakeholders in developing our implementation strategy for the transition of 10- and 90-day global services to 0-day global services.

Comment: Several commenters urged CMS to consult with stakeholders as we develop appropriate plans for the global period transition. These commenters cautioned that the structural reorganization of these services is challenging due to the large set of services that will be impacted and could potentially disrupt well-established payment for certain providers.

Response: We appreciate these recommendations and agree that we should continue to consult with stakeholders regarding the implementation of this proposal.

After consideration of all the comments received regarding this proposal, we are finalizing the proposal to transition and revalue all 10- and 90-day global surgery services with

0-day global periods, beginning with the 10-day global services in CY 2017 and following with the 90-day global services in CY 2018. We note that as we develop implementation details, including revaluations, we will take into consideration all of the comments we received to our global surgery proposal. We will provide additional details during the CY 2016 rulemaking. We are finalizing a transformation to 0-day global codes because we believe this is the most straightforward way to improve the accuracy of valuation for the various components of global surgical packages, including pre- and post-operative visits and performance of the surgical procedure. However, we remain committed to delivery system reform and ensuring Medicare makes appropriate payment for bundles of services whether our payment covers a period of 0, 10 or 90 days. As we begin revaluation of services as 0-day globals, we will actively assess whether there is a better construction of a bundled payment for surgical services.

We also actively seek the analysis and perspective of all affected stakeholders regarding the best means to revalue these services as 0-day global codes. We urge all stakeholders to engage with us regarding potential means of making the transition as seamless as possible, both for patient care and provider impact. We are considering a wide range of approaches to all details of implementation from revaluation to communication and transition, and we are hopeful that sufficient agreement can be reached among stakeholders on important issues such as revaluation of the global services and appropriate coding for post-operative care. We remain committed to collecting objective data regarding the number of visits typically furnished during post-operative periods and will explore the extant source options presented by commenters as we consider other options as well.

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

The CPT manual includes more than 300 diagnostic and therapeutic procedures, listed in Appendix G, for which CPT has determined that moderate sedation is an inherent part of furnishing the procedure and, therefore, only the single procedure code is appropriately reported when furnishing the service and the moderate sedation. The work of moderate sedation has been included in the work RVUs for these diagnostic and therapeutic procedures based upon their inclusion in Appendix G. Similarly, the direct PE inputs for these services include those inputs associated with furnishing a typical moderate sedation service. To the extent that moderate sedation is typically furnished as part of the diagnostic or therapeutic service, the inclusion of moderate sedation in the valuation of the procedure is appropriate.

In the CY 2014 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. For example, one study showed that while the use of a separate anesthesia professional for colonoscopies and upper endoscopies was just 13.5 percent in 2003, the rate more than doubled to 30.2 percent in 2009. An analysis of Medicare claims data showed that a similar pattern is occurring in the Medicare program. We found that, for certain types of procedures such as digestive surgical procedures, a separate anesthesia service is furnished 53 percent of the time. For some of these digestive surgical procedures, the claims analysis showed that this rate was as high as 80 percent.

Our data clearly indicated that moderate sedation was no longer typical for all of the procedures listed in CPT's Appendix G, and, in fact, the data suggested that the percent of cases in which it is used is declining. For many of these procedures in Appendix G, moderate sedation continued to be furnished. The trend away from the use of moderate sedation toward a separately billed anesthesia service was not universal. We found that it differed by the class of procedures, sometimes at the procedure code level, and continued to evolve over time. Due to

the changing nature of medical practice in this area, we noted that we were considering establishing a uniform approach to valuation for all Appendix G services for which moderate sedation is no longer inherent, rather than addressing this issue at the procedure level as individual procedures are revalued.

We sought public comment on approaches to address the appropriate valuation of these services. Specifically, we were interested in approaches to valuing Appendix G codes that would allow Medicare to pay accurately for moderate sedation when it is furnished while avoiding potential duplicative payments when separate anesthesia is furnished and billed. To the extent that Appendix G procedure values are adjusted to no longer include moderate sedation, we requested suggestions as to how moderate sedation should be reported and valued, and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

We noted that in the CY 2014 PFS final rule with comment period, we established values for many upper gastrointestinal procedures, 58 of which were included in Appendix G. For those interim final values, we included the inputs related to moderate sedation. We stated that we did not expect to change existing policies for valuing moderate sedation as inherent in these procedures until we have the opportunity to assess and respond to the comments on the proposed rule on the overall valuation of Appendix G codes.

We received many helpful suggestions in response to our comment solicitation. At this time, we are not making any changes to how we value Appendix G codes for which moderate sedation is an inherent part of the procedure. We intend to address this topic in future notice and comment rulemaking, taking into account the comments we received. In section II.G. of this CY 2015 PFS final rule with comment period, we address interim final values and establish CY 2015 inputs for the lower gastrointestinal procedures, many of which are also listed in Appendix G.

C. Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work; PE; and malpractice (MP) expense. As required by section 1848(c) 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. For CY 2015, we are proposing to implement the third comprehensive review and update of MP RVUs. For details about prior updates, see the CY 2010 final rule with comment period (74 FR 33537).

2. Methodology for the Proposed Revision of Resource-Based Malpractice RVUs

The proposed MP RVUs were calculated by a CMS contractor based on updated MP premium data obtained from state insurance rate filings. The methodology used in calculating the proposed CY 2015 review and update of resource-based MP RVUs largely paralleled the process used in the CY 2010 update. The calculation required using information on specialty-specific MP premiums linked to a specific service based upon the relative risk factors of the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, the MP premium information were weighted geographically and by specialty. Accordingly, the proposed MP RVUs were based upon three data sources: CY 2011 and CY 2012 MP premium data; CY 2013 Medicare payment and utilization data; and CY 2015 proposed work RVUs and geographic practice cost indices (GPCIs).

Similar to the previous update, we calculated the proposed MP RVUs using specialty-specific MP premium data because they represent the actual expense incurred by practitioners to obtain MP insurance. We obtained and used MP premium data from state

departments of insurance rate filings, primarily for physicians and surgeons. When the state insurance departments did not provide data, we used state rate filing data from the Perr and Knight database, which derives its data from state insurance departments. We used information obtained from MP insurance rate filings with effective dates in 2011 and 2012. These were the most current data available during our data collection process.

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

We included premium information for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Most insurance companies provided crosswalks from insurance service office (ISO) codes to named specialties. We matched these crosswalks to Medicare primary specialty designations (specialty codes). We also used information we obtained regarding surgical and nonsurgical classes. Some companies provided additional surgical subclasses; for example, distinguishing family practice physicians who furnish obstetric services from those who do not.

Although we collected premium data from all states and the District of Columbia, not all specialties had premium data in the rate filings from all states. Additionally, for some specialties, MP premiums were not available from the rate filings in any state. Therefore, for specialties for which there was not premium data for at least 35 states, and specialties for which there was not distinct premium data in the rate filings, we crosswalked the specialty to a similar specialty, conceptually or by available premium data, for which we did have sufficient and reliable data. Additionally, we crosswalked three specialties – physician assistant, registered dietitian and optometry – for which we had data from at least 35 states to a similar specialty type because the available data contained such extreme variations in premium amounts that we found it to be unreliable. The range in premium amounts for registered dietitians is $85 to $20,813 (24,259 percent), for physician assistants is $614 to $35,404 (5,665 percent), and for optometry is $189 to $10,798 (5,614 percent). We crosswalked these specialties to allergy and immunology, the specialty with the lowest premiums for which we had sufficient and reliable data.

Our proposed methodology for updating the MP RVUs conceptually followed the specialty-weighted approach, used in the CY 2010 update. The specialty-weighted approach bases the MP RVUs for a given service upon a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are accounted for in the calculation of the MP RVUs. We also continued to use the risk factor of the dominant specialty for rarely billed services (that is, when CY 2013 claims data reflected allowed services of less than 100).

We proposed minor refinements for updating the CY 2015 MP RVUs as compared to the previous update. These refinements included calculating a combined national average surgical premium and risk factor for neurosurgery and neurology and updating the list of invasive

cardiology service HCPCS codes (for example, cardiac catheterization and angioplasty) to be classified as surgery for purposes of assigning service level risk factors. Additionally, we proposed to classify injection procedures used in conjunction with cardiac catheterization as surgery (for purposes of assigning a service specific risk factor). To calculate the risk factor for TC services we proposed to use the mean umbrella non-physician MP premiums obtained from Radiology Business Management Association (RBMA) survey data, used for the previous MP RVU update in 2010, and adjusted the premium data to reflect the change in non-surgical premiums for all specialties since the previous MP RVU update.

As discussed in the CY 2015 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 intend to propose an anesthesia adjustment for MP in the CY 2016 PFS proposed rule. We also requested comments on how to reflect updated MP premium amounts under the anesthesiology fee schedule.

We posted our contractors report, "Report on the CY 2105 Update of Malpractice RVUs" on the CMS website. The report on MP RVUs for the CY 2015 proposed rule and the proposed MP premium amounts and specialty risk factors are accessible from the CMS website under the supporting documents section of the CY 2015 PFS proposed rule at http://www.cms.gov/PhysicianFeeSched/. A more detailed explanation of our proposed MP RVU update can be found in the CY 2015 PFS proposed rule (79 FR 40349 through 40355).

3. Response to Public Comments

We received over 70 industry comments on the CY 2015 proposed MP RVU update. A summary of the comments we received on the proposed MP RVU update and our responses are discussed below.

Comment: Two commenters supported our proposal to combine the surgical premium data for neurosurgery and neurology for establishing the surgical risk factor for neurosurgery.

Response: We agree with the commenters and will finalize our approach for determining the surgical premium for neurosurgery as proposed. We will combine surgical premiums for neurology and neurosurgery to calculate a national average surgical premium and risk factor for neurosurgery.

Comment: Three commenters requested that we phase in the reduction for ophthalmology and optometry services over 2 years. The commenters stated that the reduction is due in part to an error we made in calculating the MP RVUs for ophthalmology and optometry codes under the previous MP RVU update in CY 2010. The commenters stated that an immediate implementation of the correction would result in significant payment reductions for ophthalmologists.

Response: We note that for the CY 2015 MP RVU update we did not correct the mistake that was made in CY 2010. For the CY 2015 MP update we recalculated the MP RVUs based upon the most recently available data for all services, including ophthalmic services. Accordingly, the proposed MP RVU update reflects the use of updated MP premium data and risk factors by specialty and is not affected in any way by the CY 2010 MP RVUs. In doing so, even though the proposed CY 2015 ophthalmology non-surgical risk factor was 14 percent greater than the CY 2010 non-surgical risk factor and the proposed surgical risk factor was 17 percent greater, the proposed MP RVUs for most services with significant ophthalmology volume decreased because the CY 2010 error resulted in MP RVUs that were higher than they should have been. That is, the reduction in MP RVUs for ophthalmology and optometry are solely due to overpayments made due to a mistake during the previous MP RVU update rather than a proposed change in methodology or the use of updated premium data. We do not believe

that a previous error is sufficient justification for not fully implementing updated MP RVUs based on more recent premium data. Therefore, we will implement the updated MP RVUs for ophthalmology and optometry services as proposed.

Comment: We received comments regarding the application of our specialty weighted approach for calculating service level risk factors for surgical services. For instance, the same commenters that requested a 2-year phase in of the reduction to ophthalmology services also requested that we exclude optometry from calculating the risk factor for ophthalmic surgery. One commenter stated that "MP RVUs for cataract and other ophthalmic surgeries are deflated because CMS assumes that optometry is providing the surgical portion of the procedure." The commenter also stated that optometrists are involved only during the pre- or post-procedure periods of ophthalmic surgery. Another specialty society stated that it appears that CMS's methodology for calculating service level risk factors for surgical services "may include the allowed services for surgical assistance possibly discounted to reflect the assistant role under payment policy." The commenter also stated that "specialties that assist at the procedure do not perform it, and the assistant's associated MP risk factor has no bearing on the MP cost for the surgeon."

Response: The commenter is correct to say that we calculated service level risk factors based on the mix of all practitioners billing for a given service and that the specialty weighted approach is applied to both surgical and non-surgical services . That is, we apply the risk factor(s) of all specialties involved with furnishing the surgical procedure to calculate service level risk factors and MP RVUs. For assistants at surgery, we discount the utilization to reflect his or her role in furnishing the surgical procedure. Although we agree that MP cost for the surgeon may not be affected by the surgical assistant's MP cost, we do not agree with the suggestion that assistants at surgery should be excluded from our specialty weighted approach

for determining service level MP risk factors and MP RVUs for surgical services. We believe it is appropriate to apply the specialty risk factor(s) of all practitioners participating in and receiving a payment for the surgical procedure for purposes of determining a service level risk factor and thus the payment for that service. 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. Similarly, we also disagree with the suggestion that 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 MP costs.

We note that in both of these cases by using the discounted utilization file the weighted average that we use reflects only the proportion of the utilization by these practitioners and only at the payment rate made. Including specialty utilization for all practitioners involved in furnishing the global service reflects the MP risk for the entire global service.

Comment: We received two comments regarding how risk factors are assigned to existing services without Medicare utilization. The commenters stated that we crosswalk to the risk factor of an analogous source code with Medicare utilization for new codes but assign the average risk factor for all physicians to existing services without Medicare utilization. The commenters contend that "it is inappropriate for a service to have fluctuating MP risk factors simply due to whether it is reported in Medicare claims data for a given year." The commenters requested that we crosswalk existing services without Medicare utilization to a recommended source code.

Response: We used the most recently available Medicare claims data (that is, from CY 2013) to determine the service level risk factors, either based on the risk factors of the actual mix of practitioners furnishing the service, or in the case of low volume services, the risk factor of the dominant specialty. We disagree with the commenters' suggestion to assign the risk factor of a recommended specialty to an existing service without Medicare utilization as indicated by our most recently available claims data. In the absence of Medicare utilization we continue to believe that the most appropriate risk factor is the weighted average risk factor for all service codes. The proposed weighted average risk factor for all service codes was 2.11. Using the weighted average risk factor for all services effectively neutralizes the impact of updated MP premiums and risk factors for any specific specialty (or mix of specialties).

Comment: The AMA and the RUC and other commenters agreed with the majority of our proposed claims based dominant specialty designations for codes with less than 100 allowed services; however, the commenters disagreed with our proposed dominant specialty for some services. The commenters believe that some claims have been miscoded, resulting in erroneous specialty designations. One commenter stated that using the dominant specialty from the claims data resulted in unjustifiably low MP RVUs for congenital heart surgery. The commenter stated that congenital heart surgery can only be done by a heart surgeon and requested that we override the dominant specialty in our claims data and use the RUCs recommended specialty.

Response: As discussed in the previous response, we proposed to use CY 2013 claims data to determine the service level MP risk factors, either based on the mix of practitioners furnishing the service, or in the case of low volume services, assigning the risk factor of the dominant specialty. We continue to believe that use of actual claims data to determine the dominant specialty is preferable to using a "recommended" specialty. However, we recognize that anomalies in the claims data can occur that would affect the dominant specialty for low

volume services, and therefore resulting in the need for a subjective review of some services in place of a complete reliance on claims data. To that end, we reviewed the commenter's recommendations for overriding the dominant specialty from our claims data with a recommended specialty. After careful consideration of the comments, we will override the dominant specialty from Medicare claims data when the dominant specialty from our claims data is inconsistent with a specialty that could be reasonably expected to furnish the service. For example, our claims data indicates that pulmonary disease is the dominant specialty for HCPCS code 33622 (Reconstruction of complex cardiac anomaly), however as the commenter mentioned, this service is furnished by heart surgeons. A complete listing of low volume services for which we will override the claims based dominant specialty with the recommended specialty to assign a service level risk factor is illustrated in Table 12.

TABLE 12: Low Volume Service Codes Where Assigned Specialty Used Rather than Claims Based Dominant Specialty

HCPCS Code	Short Descriptor	Claims Based Dominant Specialty	Assigned Specialty
25490	Reinforce radius	Otolaryngology	Orthopedic Surgery
26556	Toe joint transfer	Pulmonary Disease	Orthopedic Surgery
31320	Diagnostic incision larynx	Cardiology	Otolaryngology
33620	Apply r&l pulm art bands	Anesthesiology	Cardiac Surgery
33621	Transthor cath for stent	Cardiology	Cardiac Surgery
33622	Redo compl cardiac anomaly	Pulmonary Disease	Cardiac Surgery
33697	Repair of heart defects	Cardiology	Cardiac Surgery
33766	Major vessel shunt	General Surgery	Cardiac Surgery
36261	Revision of infusion pump	General Practice	General Surgery
43341	Fuse esophagus & intestine	Gastroenterology	Thoracic Surgery
43350	Surgical opening esophagus	General Practice	General Surgery
49491	Rpr hern preemie reduc	General Practice	General Surgery
50686	Measure ureter pressure	Internal Medicine	Urology
54352	Reconstruct urethra/penis	Pediatric Medicine	Urology
54380	Repair penis	Gastroenterology	Urology
61000	Remove cranial cavity fluid	Family Practice	Neurosurgery
61558	Excision of skull/sutures	Family Practice	Neurosurgery
61567	Incision of brain tissue	Cardiology	Neurosurgery
74710	X-ray measurement of pelvis	Thoracic Surgery	Diagnostic Radiology
96003	Dynamic fine wire emg	Cardiology	Physical Therapist/Independent Practice
96420	Chemo ia push technique	Urology	Hematology Oncology
99170	Anogenital exam child w imag	Ophthalmology	Pediatric Medicine
99461	Init nb em per day non-fac	Cardiac Electrophysiology	Pediatric Medicine

Comment: Some commenters requested that we crosswalk gynecological oncology to general surgery, instead of crosswalking to obstetrics/ gynecology because gynecological oncology is more akin to general surgery procedures than obstetrics/gynecology. One specialty society stated that gynecological oncologists are predominantly cancer surgeons with MP risk similar to general surgery.

Response: We agree with the commenters and will crosswalk gynecological oncology to the general surgery premium data and risk factor.

Comment: One commenter requested that we crosswalk clinical laboratory to pathology instead of the risk factor used for TC services because clinical laboratories and pathologists render essentially identical medical procedures that are paid on the Medicare PFS.

Response: We believe that the MP risk for clinical laboratories is more akin to the MP risk of radiation therapy centers, mammography screening centers and IDTFs, for which we assigned the TC risk factor, than to the MP risks for pathologists. The commenters did not provide sufficient rationale to support that MP risk for clinical laboratories is similar to the MP risk of pathologists. Therefore, we will crosswalk clinical laboratory to the TC risk factor as proposed.

Comment: One commenter encouraged us to crosswalk the interventional pain management specialty to a specialty that more closely reflects the risks and services associated with interventional pain management, such as interventional radiology or a comparable surgical subspecialty.

Response: We believe that the MP risk associated with interventional pain management is conceptually similar to the MP risk for anesthesiology more so than to the MP risk for interventional radiology. Given that the commenters did not provide sufficient rationale to support that MP risk for interventional pain management is similar to interventional radiology or to a comparable surgical specialty, we will crosswalk interventional pain management to anesthesiology as proposed.

Comment: We received contrasting comments on our proposal to crosswalk NPPs to the premium and risk factor calculated for allergy/immunology. For instance, one commenter acknowledged the difficulty in identifying comprehensive, accurate premium data across the majority of states, especially for NPPs. To that end, the commenter supported our decision to crosswalk the MP premiums of NPPs to the lowest physician risk factor, allergy/immunology.

Another commenter, specifically supported crosswalking registered dieticians to the risk factor calculated for allergy/immunology.

In contrast, the AMA and other commenters did not support crosswalking NPPs with insufficient or unreliable premium data to the premium amounts and risk factor used for allergy/immunology. The commenters stated that allergy/immunology premiums overstate NPP premiums and requested that we use the generally lower MP survey data from the Physician Practice Information Survey (PPIS) for NPPs instead of crosswalking NPPs to the lowest physician specialty (allergy/immunology) or use some other measure of central tendency within the existing collected premium data to determine accurate MP premium risk factors for NPPs. Another commenter suggested that we work with the AMA to obtain the necessary data to ensure the process for reviewing and updating MP rates is accurate for all providers.

Response: As discussed previously in this section, the resource-based MP RVUs are based on verifiable MP premium data. We do not believe it would be appropriate to base the MP RVUs for nonphysician specialties on survey data and use premium data for all other specialties. Therefore, we do not agree with the commenters that suggested using survey data for NPPs and will finalize the specialty crosswalks for NPPs as proposed. However, in light of the commenter's suggestions, we will explore ways to enhance our MP premium data collection efforts to obtain better premium data for NPPs for future updates. We will also explore other potential measures of central tendency for determining the "indexed" specialty as an alternative to using the premium values of the lowest specialty.

Comment: We received two comments regarding the data and or methodology used to calculate the TC and PC of diagnostic services. One specialty group noted that the proposed MP RVUs for the TC of some diagnostic services increased while the MP RVUs for the PC decreased. Specifically, the commenter questioned why the MP RVUs for the PC of diagnostic

cardiac catheterization as described by HCPCS codes 93451 through 93461 decreased by 6 to 12 percent while the TC portion for these codes increased by 20 to 33 percent. The commenter encouraged us to review the reasons for this shift to TC MP RVUs. Additionally, the RBMA submitted updated MP premium information collected from IDTFs in 2014. The RBMA requested that we use the recently obtained data reflecting the median "50th percentile" premium data for "umbrella non-physician MP liability" for calculating CY 2015 MP RVUs for TC services.

Response: To calculate the risk factor for TC services we used the mean umbrella non-physician MP premiums obtained from the RBMA survey data (used for the previous MP RVU update in 2010) and adjusted the data to reflect the change in non-surgical premiums for all specialties since the previous MP RVU update, for example, $9,374 deflated by -20.41 percent = $7,455. However, given that the premiums of the lowest physician specialty (allergy/immunology) decreased by more than 20 percent, the proposed CY 2015 risk factor for TC services increased from the previous update in CY 2010 from 0.86 to 0.91, resulting in minor increases in MP RVUs for TC services. However, given that the MP RVUs for TC services are generally low, any increase to the MP RVUs could result in a significant percentage increase. For example, the proposed CY 2015 MP RVU for HCPCS code 93455 increased from 0.04 to 0.05 yielding a 25 percent increase. Therefore, a minor increase in MP RVUs for a TC service could result in a significant percentage change.

We believe that using the updated RBMA premium data without further study is problematic because the updated data reflects only the median umbrella non-physician MP premium, rather than the mean as was used for the 2010 MP RVU update and the proposed 2015 MP RVU update.

We believe further study is necessary to reconcile comments on the use of updated RBMA premium data for TC services (which would result in an increase MP RVU for TC services) and our current methodology for calculating the risk factor for PC services relative to the global service and TC service. Therefore, we will finalize the TC premium data as proposed and maintain our current methodology for calculating the PC risk factor. We will consider the request to use the updated premium information from RBMA and alternatives to our current methodology for calculating the PC risk factor as part of our further study and would propose any changes through future rulemaking.

Comment: Several commenters supported our proposal to classify cardiac catheterization and angioplasty services as surgical procedures for the purpose of establishing service level risk factors. The commenters also agreed with our proposal to apply the surgical risk factor to injection procedures used in conjunction with cardiac catheterization. The same commenters identified additional cardiac catheterization and angioplasty services that were not included on the proposed list of invasive cardiology services. Specifically, the commenters requested that we consider adding HCPCS codes 92961, 92986, 92987, 92990, 92992, 92993, 92997, and 92998 to the list of invasive cardiology procedures classified as surgery for purposes of assigning service level risk factors because the MP risk for these services is similar to surgery.

Response: We agree that the MP risk associated with the cardiac catheterization and angioplasty services mentioned by the commenters are more akin to surgical procedures than most non-surgical services. Therefore, we will add cardiac catheterization and angioplasty services as described by HCPCS codes 92961, 92986, 92987, 92990, 92997, and 92998 to the list of services outside of the surgical HCPCS code range to be considered surgery for purposes of assigning service level MP risk factors. We note that HCPCS codes 92992 and 92993 are contractor-priced codes, wherein the Medicare claims processing contractors establish RVUs and

payment amounts for these services. Therefore, we are not adding HCPCS codes 92992 and 92993.

Comment: One commenter stated that several injection codes were not included in the list of services outside of the surgical HCPCS code range considered surgery. The commenter requested that we add injection services as described by HCPCS codes 93565, 93566, 93567, and 93568 to the services considered as surgery.

Response: The commenter is mistaken. As discussed in the CY 2015 proposed rule (79 FR 40353 through 40354), we included the injection procedure codes mentioned by the commenter on the list of services outside of the surgical HCPCS code range to be considered surgery for purposes of assigning service level MP risk factors.

Comment: One commenter questioned why the MP RVUs decrease for cardiac catheterization services as described by HCPCS codes 93530, 93531 and 93580. The commenter stated that our proposal to assign the surgical risk factor to invasive cardiology services outside of the surgical HCPCS code range should result in an increase in MP RVUs.

Response: Cardiac catheterizations as described by HCPCS codes 93530, 93531 and 93580 are currently on the list of invasive cardiology services classified as surgery for purposes of assigning service level risk factors. Therefore, the MP RVUs for HCPCS codes 93530, 93531, 93580 were calculated in the last update using the surgical risk factor applicable to the specialty(s) furnishing these services. As discussed previously in this section, the service level risk factors reflect the average risk factor (weighted by allowed services) of the specialties furnishing a given service. Changes in the specialty mix since the previous MP RVU update in 2010 resulted in a decrease in MP RVUs for HCPCS codes 93530, 93531, and 93580. That is, the percentage of allowed services attributed to cardiology decreased for these service codes

while the percentage of allowed services furnished by other specialties with risk factors lower than cardiology, such as internal medicine and pediatric medicine, increased.

Comment: Many commenters requested an explanation as to why the MP RVUs decreased for 4 out of the 6 newly bundled image guided breast biopsy procedures. The commenters stated that given that the MP RVUs assigned to breast biopsy codes are being reduced, CMS is not appropriately capturing the risk a physician assumes when performing a procedure to diagnose cancer. Several commenters also explained that the misdiagnosis of breast cancer is a leading source of MP litigation and that reduction in payment for breast biopsies will have an impact on patient care.

Response: For the image guided breast biopsy procedures as described by HCPCS codes 19081 through 19086, we used the risk factors from source codes as recommended by the RUC. The source codes for breast biopsy codes 19081, 19082, 19083, 19084, 19085 and 19086 are HCPCS codes 32553, 64480, 32551, 64480, 36565, and 76812, respectively. Given that the proposed risk factors for HCPCS codes 32553, 64480, and 32551 decreased from 2014 to 2015, the corresponding "destination" service codes, that is HCPCS codes 19081, 19082, 19083, and 19084 also decreased.

Comment: Several commenters recommended that we implement an annual collection and review of MP premium data and rescale the MP RVUs each year, as we do with the PE RVUs. The commenters also stated that an annual update would provide additional transparency and allow stakeholders to identify potential problems and or improvements to MP RVUs more frequently.

Response: We appreciate the comments from stakeholders regarding the frequency that we currently review changes in MP premium data. As discussed in the CY 2015 PFS proposed rule (79 FR 40349 through 40355), there are two main aspects to the update of MP RVUs,

recalculation of specialty risk factors based upon updated premium data and recalculation of service level RVUs based upon the mix of practitioners providing the service. We will consider the recommendation from stakeholders to conduct annual MP RVU updates to reflect corrections and changes in the mix of practitioners providing services. We will also consider the appropriate frequency for collecting new MP premium data. After reviewing these issues, we would address potential changes regarding the frequency of MP RVU updates in a future proposed rule.

Comment: One commenter urged us to calculate risk factors for all specialties approved by the American Board Medical Specialties (ABMS) since 2010. The commenter stated that by using the approved ABMS specialties, all specialties and subspecialties will be represented, including the recently approved sub-specialty of Female Pelvic Medicine and Reconstructive Surgery.

Response: We calculate service level risk factors based on the mix of specialties that furnish a given service as indicated by our claims data. Medicare claims data reflects the service volume by Medicare primary specialty designations. Therefore, we can only use MP risk factors by Medicare primary specialty codes.

Comment: We received two comments regarding our discussion of how to reflect updated MP premium data under the anesthesiology fee schedule. One commenter supported our decision to delay the anesthesia MP update and requested to work with us on developing an appropriate method for updating the MP component associated with anesthesia fee schedule services. 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. The commenter stated that the calculation of premiums over a longer period of time renders the average more accurate and less volatile than a calculation over a 1-year period.

Response: We appreciate the comments on our potential approach for updating the MP resource costs for anesthesia fee schedule services. We will consider the commenter's suggestions to use multi-year average premiums as we develop a method for updating MP payments for services paid on the anesthesia fee schedule.

4. Result of Evaluation of Comments

After consideration of the public comments received on the CY 2015 MP RVU update, we are finalizing the CY 2015 MP RVU update as proposed with minor modifications. We are crosswalking gynecological oncology to the risk factor for general surgery (instead of the risk factor for obstetrics gynecology). We are also adding HCPCS codes 92961, 92986, 92987, 92990, 92997, and 92998 to the list of services outside of the surgical HCPCS code range considered as surgery for purposes of assigning service level risk factors. Additionally, for determining the risk factor for low volume services, we are overriding the dominant specialty from our claims data with the recommended specialty for the low volume service codes listed in Table 12. For all other low volume services, we are finalizing our proposal to use the risk factor of the dominant specialty from our Medicare claims data. The MP premium amounts, specialty risk factors, and a complete list of service codes outside the surgical HCPCS code range considered surgery for the purpose of assigning service level risk factors, may be found on the CMS website under the supporting documents section of the CY 2015 PFS final rule with comment period.

Additional information on the CY 2015 update may be found in our contractor's report, "Final Report on the CY 2105 Update of Malpractice RVUs," which is available 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/.

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). Although the statute requires that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire on March 31, 2014. However, section 102 of the PAMA extended application of the 1.0 floor to the work GPCI through March 31, 2015.

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that "if more than 1 year has elapsed since the date of the last previous adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made." We completed a review and finalized updated GPCIs in the CY 2014 PFS final rule with comment period (78 FR 74390). Since the last GPCI update had been implemented over 2 years prior, CY 2011 and CY 2012, we phased in 1/2 of the latest GPCI adjustment in CY 2014. We also revised the cost share weights that correspond to all three GPCIs in the CY 2014 PFS final rule with comment period. We calculated a corresponding geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and MP GPCIs using

the national GPCI cost share weights. Although the GAFs are not used in computing the fee schedule payment for a specific service, we provide them because they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As previously noted, section 102 of the PAMA extended the 1.0 work GPCI floor through March 31, 2015. Therefore, the CY 2015 work GPCIs and summarized GAFs were revised to reflect the 1.0 work floor. Additionally, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2015.

Comment: A few commenters requested that we extend the 1.0 work GPCI floor beyond March 31, 2015.

Response: As discussed in section II.D.1, the 1.0 work GPCI floor is established by statute and expires on March 31, 2015. We do not have authority to extend the 1.0 work GPCI floor beyond March 31, 2015.

As discussed in the CY 2014 PFS final rule with comment period (78 FR 74380) the updated GPCIs were calculated by a contractor to CMS. We used updated Bureau of Labor and Statistics Occupational Employment Statistics (BLS OES) data (2009 through 2011) as a replacement for 2006 through 2008 data for purposes of calculating the work GPCI and the employee compensation component and purchased services component of the PE GPCI. We also used updated U.S. Census Bureau American Community Survey (ACS) data (2008 through 2010) as a replacement for 2006 through 2008 data for calculating the office rent component of the PE GPCI. To calculate the MP GPCI we used updated malpractice premium data (2011 and 2012) from state departments of insurance as a replacement for 2006 through 2007 premium

data. We also noted that we do not adjust the medical equipment, supplies and other miscellaneous expenses component of the PE GPCI because we continue to believe there is a national market for these items such that there is not a significant geographic variation in relative costs. Additionally, we updated the GPCI cost share weights consistent with the modifications made to the 2006-based MEI cost share weights in the CY 2014 final rule with comment period. As discussed in the CY 2014 final rule with comment period, use of the revised GPCI cost share weights changed the weighting of the subcomponents within the PE GPCI (employee wages, office rent, purchased services, and medical equipment and supplies). For a detailed explanation of how the GPCI update was developed, see the CY 2014 final rule with comment period (78 FR 74380 through 74391).

2. Proposed Changes to the GPCI Values for the Virgin Islands Payment Locality

As discussed in the CY 2015 proposed rule (79 FR 40355 through 40356) the current methodology for calculating locality level GPCIs relies on the acquisition of county level data (when available). Where data for a specific county are not available, we assign the data from a similar county within the same payment locality. The Virgin Islands have county level equivalents identified as districts. Specifically, the Virgin Islands are divided into 3 districts: Saint Croix; Saint Thomas; and Saint John. These districts are, in turn, subdivided into 20 sub-districts. Although the Virgin Islands are divided into these county equivalents, county level data for the Virgin Islands are not represented in the BLS OES wage data. Additionally, the ACS, which is used to calculate the rent component of the PE GPCI, is not conducted in the Virgin Islands, and we have not been able to obtain malpractice insurance premium data for the Virgin Islands payment locality. Given the absence of county level wage and rent data and the insufficient malpractice premium data by specialty type, we have historically set the three GPCI values for the Virgin Islands payment locality at 1.0.

For CY 2015, we explored using the available data from the Virgin Islands to more accurately reflect the geographic cost differences for the Virgin Islands payment locality as compared to other PFS localities. Although county level data for the Virgin Islands are not represented in the BLS OES wage data, aggregate territory level BLS OES wage data are available. We believe that using aggregate territory level data is a better reflection of the relative cost differences of operating a medical practice in the Virgin Islands payment locality as compared to other PFS localities than the current approach of assigning a value of 1.0. At our request, our contractor calculated the work GPCI, and the employee wage component and purchased services component of the PE GPCI, for the Virgin Islands payment locality using aggregated 2009 through 2011 BLS OES data.

As discussed in this section, the ACS is not conducted in the Virgin Islands and we have not been able to obtain malpractice premium data for the Virgin Islands payment locality. Therefore, we assigned a value of 1.0 for the rent index of the PE GPCI and to the MP GPCI.

Using aggregate territory-level BLS OES wage data resulted in a -2.3 percent decrease in the work GPCI, a -4.48 percent decrease in the PE GPCI and a -3.2 percent decrease to the GAF for the Virgin Islands payment locality. However, with the application of the 1.0 work GPCI floor, there is no change to the work GPCI and the overall impact of using actual BLS OES wage data on the Virgin Islands payment locality is only reflected by the change in PE GPCI (-4.48 percent) resulting in a - 2.00 percent decrease to the GAF. As mentioned previously in this section, since we have not been able to obtain malpractice premium data for the Virgin Islands payment locality we maintained the MP GPCI at 1.0. As such, we did not propose any changes to the MP GPCI.

We requested comments on our proposal to use aggregate territory-level BLS OES wage data to calculate the work GPCI and the employee wage component and purchased services

component of the PE GPCI for the Virgin Islands payment locality beginning for CY 2015, and for future GPCI updates. However, we did not receive any specific comments on this proposal. As discussed above, we believe that using aggregate territory level BLS OES wage data is a better reflection of the relative cost differences of operating a medical practice in the Virgin Islands payment locality as compared to other PFS localities than the current approach of assigning a value of 1.0. Therefore, we will finalize the changes to the GPCI values for the Virgin Islands payment locality as proposed. See Addenda D and E for the CY 2015 GPCIs and summarized GAFs. Additional information on the changes to GPCI values for the Virgin Islands payment locality may be found in our contractor's report, "Revised Final Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on the CMS website. It is located under the supporting documents section of the CY 2015 PFS final rule with comment period located at http://www.cms.gov/PhysicianFeeSched/.

3. Additional Comments

We received several comments on topics that are not within the scope of proposals in the CY 2015 PFS proposed rule. These comments are briefly discussed below.

Comment: Many commenters continued to request an increase in the GPCI values for the Puerto Rico payment locality. The commenters stated that the cost of practicing medicine in Puerto Rico continues to rise. The commenters believe that commercial rent and utility costs, and the cost of obtaining medical equipment and supplies are higher in Puerto Rico than many states and territories. Commenters contend that the data used to calculate GPCIs do not accurately reflect the cost of operating a medical practice in Puerto Rico.

Response: Aside from proposing to use territory-wide wage data for the Virgin Islands payment locality, we finalized the methodology and values for the 7th GPCI update in the CY

2014 PFS final rule with comment period. We did not propose any changes to the GPCIs for the Puerto Rico payment locality, and the commenters on the CY 2015 PFS proposed rule raised the same issues they raised in response to the proposed GPCI update that we finalized in CY 2014. In the CY 2014 PFS final rule with comment period (78 FR 74380 through 74391), we summarized these comments and responded to these issues.

Comment: A few commenters stated that GPCIs for rural areas are too low which leads to reduced numbers of rural practitioners and reduced access to care. Two commenters stated that the PE GPCI does not account for differences in practice costs for x-rays and imaging studies. The same commenters and another commenter also requested that we replace the current method for calculating the work GPCIs with one that reflects the labor market for physicians and other health professionals as recommended by MedPAC. Another commenter raised questions about state patient compensation fund surcharges for malpractice insurance and the implications of those for the MP GPCI values. Additionally, we received a comment about the physician fee schedule payment localities.

Response: As noted in this section, we finalized the 7th GPCI update in the CY 2014 PFS final rule with comment period and, other than the proposal relating to the use of territory-wide wage data for the Virgin Islands payment locality, we did not propose any further changes in the CY 2015 PFS proposed rule. We will consider these points raised by commenters when we develop a proposal for the 8th GPCI update.

E. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met in order for Medicare payments to be made for telehealth services under the PFS. Specifically, the service must be on the list of Medicare telehealth services and meet all of the following additional requirements for coverage:

- The service must be furnished via an interactive telecommunications system.
- The practitioner furnishing the service must meet the telehealth requirements, as well as the usual Medicare requirements.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays an originating site fee to the originating site and provides 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 electronic mail systems do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous ''store-and-forward'' technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at §410.78(a)(1), store-and-forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

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 means an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

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

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare Administrative Contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the

amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

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

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

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

Effective January 1, 2014, we also changed our policy so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other

telehealth payment policies (78 FR 74400). Geographic eligibility 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 with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a

telecommunications system in furnishing the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

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

For the list of covered telehealth services, see the CMS website at www.cms.gov/teleheath/. Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2014 will be considered for the CY 2016 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 www.cms.gov/telehealth/.

3. Submitted Requests to the List of Telehealth Services for CY 2015

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

a. Submitted Requests

We received several requests in CY 2013 to add various services as Medicare telehealth services effective for CY 2015. The following presents a discussion of these requests, and our proposals for additions to the CY 2015 telehealth list. Of the requests received, we find that the following services are sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category one basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2015:

- CPT codes 90845 (Psychoanalysis); 90846 (family psychotherapy (without the patient present); and 90847 (family psychotherapy (conjoint psychotherapy) (with patient present);
- CPT codes 99354 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (list separately in addition to code for office or other outpatient evaluation and management service); and, 99355 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service); and,
- HCPCS codes G0438 (annual wellness visit; includes a personalized prevention plan of service (pps), initial visit; and, G0439 (annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit).

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

- CPT codes 92250 (fundus photography with interpretation and report); 93010 (electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), 93307 (echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color Doppler echocardiography; 93308 (echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study); 93320 (Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (list separately in addition to codes for echocardiographic imaging); complete); 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); and 93325 (Doppler echocardiography color flow velocity mapping

(list separately in addition to codes for echocardiography). These services include a technical component (TC) and a professional component (PC). By definition, the TC portion of these services needs to be furnished in the same location as the patient and thus cannot be furnished via telehealth. The PC portion of these services could be (and typically would be) furnished without the patient being present in the same location. (Note: For services that have a TC and a PC, there is sometimes an entirely different code that is used when only the PC portion of the service is being furnished, and other times the same CPT code is used with a –26 modifier to indicate that only the PC is being billed.) For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted electronically, can be furnished without the patient being present in the same location as the physician. Given the nature of these services, it is not necessary to consider including the PC of these services for addition to the telehealth list. When these PC services are furnished remotely, they do not meet the definition of Medicare telehealth services under section 1834(m) of the Act. Rather, these remote services are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way as other physicians' services (that is, without the –GT or –GQ modifiers).

- CPT codes 96103 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI), administered by a computer, with qualified health care professional interpretation and report); and, 96120 (neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report). These services involve testing by computer, can be furnished remotely without the patient being present, and are payable in the

same way as other physicians' services. These remote services are not Medicare telehealth services as defined under the Act; therefore, we need not consider them for addition to the telehealth list, and the restrictions that apply to telehealth services do not apply to these services.

- CPT codes 90887 (interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist patient); 99090 (analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data); 99091 (collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time); 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). These services are not separately payable by Medicare. It would be inappropriate to include services as telehealth services when Medicare does not otherwise make a separate payment for them.

- CPT codes 96101 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); 96102 (psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face); 96118 (neuropsychological testing (eg, Halstead-Reitan Neuropsychological

Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and, 96119 (neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face). These services are not similar to other services on the telehealth list, as they require close observation of how a patient responds. The requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

- CPT codes 57452 (colposcopy of the cervix including upper/adjacent vagina; 57454 colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix and endocervical curettage); and, 57460 (colposcopy of the cervix including upper/adjacent vagina; with loop electrode biopsy(s) of the cervix). These services are not similar to other services on the telehealth service list. Therefore, it would not be appropriate to add them on a category 1 basis. The requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

- HCPCS code M0064 (brief office visit for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental psychoneurotic and personality disorders) is being deleted for CY 2015. This code was created specifically to describe a service that is not subject to the statutory outpatient mental health limitation, which limited payment amounts for certain mental health services. Section 102 of the Medicare Improvements for Patients and Providers Act (Pub. L. 110– 275, enacted on July 15, 2008) (MIPPA) required that the limitation

on payment for outpatient mental health treatment to 62.5 percent of incurred expenses, in effect since the inception of the Medicare program, be reduced over four years. This limitation on payment for mental health treatment created a higher share of beneficiary coinsurance for these services than for most other Medicare services paid under the PFS. Effective January 1, 2014, 100 percent of expenses incurred for mental health treatment services are considered as incurred for purposes of Medicare, resulting in the same beneficiary cost sharing for these services as for other PFS services. Since the statute was amended to phase out the limitation, and the phase-out was complete effective January 1, 2014, Medicare no longer has a need to distinguish services subject to the mental health limitation from those that are not. Accordingly, the appropriate CPT code can now be used to bill Medicare for the services that would have otherwise been reported using M0064 and M0064 will be eliminated as a telehealth service, effective January 1, 2015.

- Urgent Dermatologic Problems and Wound Care—The American Telemedicine Association (ATA) cited several studies to support adding dermatology services to the telehealth list. However, the request did not include specific codes. Since we did not have specific codes to consider for this request, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list. We note that some of the services that the requester had in mind may be billed under the telehealth office visit codes or the telehealth consultation G-codes.

In summary, we proposed to add the following codes to the telehealth list on a category 1 basis:

- Psychotherapy services CPT codes 90845, 90846 and 90847.
- Prolonged service office CPT codes 99354 and 99355.
- Annual wellness visit HCPCS codes G0438 and G0439.

3. Modifying §410.78 Regarding List of Telehealth Services

As discussed in section II.E.2. of this final rule with comment period, under the statute, we created an annual process for considering the addition of services to the Medicare telehealth list. Under this process, we propose services to be added to the list in the proposed rule in response to public nominations or our own initiative and seek public comments on our proposals. After consideration of public comments, we finalize additions to the list in the final rule. We have also revised §410.78(b) each year to include the description of the added services. Because the list of Medicare telehealth services has grown quite lengthy, and given the other mechanisms by which we can make the public aware of the list of Medicare telehealth services for each year, we proposed to revise §410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth. Under this proposal, we would continue our current policy to address requests to add to the list of telehealth services through the PFS rulemaking process so that the public would have the opportunity to comment on additions to the list. We also proposed to revise §410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS website.

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

Comment: All commenters supported one or more of our proposals to add psychotherapy services (CPT codes 90845, 90846 and 90847); prolonged service office (CPT codes 99354 and 99355); and annual wellness visit (HCPCS codes G0438 and G0439) to the list of Medicare telehealth services for CY 2015.

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 2015 proposal to add these services to the list of telehealth services for CY 2015 on a category 1 basis.

Comment: Commenters also agreed with our rationale for rejecting other requested additions to the telehealth list. However, one commenter disagreed with our decision not to propose adding dermatology services, including those furnished using store-and-forward technology, to the list of telehealth services. Another commenter objected to our proposal not to add psychological testing services to the telehealth services list.

Response: As we noted in the proposed rule, the request to add dermatology services did not include specific codes. Without specific codes to consider, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list. We note that some of the services that the requester had in mind may be billed under the telehealth office visit codes or the telehealth consultation G–codes.

Concerning payment for services furnished using store-and-forward technology, we note that the statute at section 1861(m) of the Act includes store-and-forward technology as a telecommunication system for telehealth services only in the case of federal telemedicine demonstration programs in Alaska and Hawaii (see §410.78(d)).

Concerning psychological testing services, we noted that remote services (CPT codes 96103 and 96120) are not Medicare telehealth services as defined under the Act and thus can be furnished when beneficiary is not in the same place as the practitioner. It would also be counter-productive to add these codes to the telehealth list because, if we did, the telehealth originating site, geographic, and other restrictions would apply to these services.

CPT codes 90887, 90991, 93358 and 99359 are not separately payable by Medicare. It would be inappropriate to include services as telehealth services when Medicare does not otherwise make a separate payment for them.

Finally, CPT codes 96101, 96102, 96118 and 96119 are not similar to other services on the telehealth list, as they require close observation of how a patient responds. The requestor did

not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis. As such, we did not propose to add these services to the list of telehealth services.

We received other public comments on matters related to Medicare telehealth services that were not the subject of proposals in the CY 2015 PFS proposed rule. Because we did not make any proposals regarding these matters, we generally do not summarize or respond to such comments in the final rule. However, we are summarizing and responding to the following comments to acknowledge the interests and concerns of the commenters, and a mechanism to address some of those concerns.

Many commenters supported the overall expansion of telehealth by:

- Removing geographic restrictions to include both rural and urban areas.
- Revising permissible originating sites to include a patient's home, domiciliary care and first responder vehicles.
- Adopting a broader definition of telehealth technologies to include services provide via mobile technology, including emails, phone calls, and store-and-forward technologies.
- Adding physical and occupational therapists as practitioners who can remotely furnish telehealth services.
- Adding more services to the telehealth list, including services under category 2.
- Prioritizing coverage of services that include care coordination with the patient's medical home and/or existing treating physicians.
- Considering the use of telehealth technology for the purpose of furnishing direct supervision of services furnished by on-site practitioners.
- Using demonstration projects under CMS's Center for Medicare and Medicaid Innovation (CMMI) to collect clinical evidence on the effect of expanding telehealth and to address how telemedicine can be integrated into new payment and delivery models.

Response: We appreciate the commenters' suggestions. As some commenters noted, we do not have authority to implement many of these revisions under the current statute. 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.

In summary, after consideration of the comments we received, we are finalizing our proposal to add psychotherapy services CPT codes 90845, 90846 and 90847; prolonged service office CPT codes 99354 and 99355; and annual wellness visit HCPCS codes G0438 and G0439 to the list of Medicare telehealth services.

In addition, we are finalizing our proposal to change our regulation at §410.78(b) by deleting the description of the individual services for which Medicare payment can be made when furnished via telehealth. We will continue our current policy to address requests to add services to the list of Medicare telehealth services through the PFS rulemaking process so that the public has the opportunity to comment on additions to the list. We are also finalizing our proposal to revise §410.78(f) to indicate that a list of Medicare telehealth codes and descriptors is available on the CMS website.

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2016, these requests must be submitted and received by December 31, 2014. 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 www.cms.gov/telehealth/.

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 2015 is 0.8 percent. Therefore, for CY 2015, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $24.83. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 13.

TABLE 13: The Medicare Telehealth Originating Site Facility Fee and MEI Increase by the Applicable Time Period

Facility Fee	MEI Increase	Period
$20.00	N/A	10/01/2001 – 12/31/2002
$20.60	3.0%	01/01/2003 – 12/31/2003
$21.20	2.9%	01/01/2004 – 12/31/2004
$21.86	3.1%	01/01/2005 – 12/31/2005
$22.47	2.8%	01/01/2006 – 12/31/2006
$22.94	2.1%	01/01/2007 – 12/31/2007
$23.35	1.8%	01/01/2008 – 12/31/2008
$23.72	1.6%	01/01/2009 – 12/31/2009
$24.00	1.2%	01/01/2010 – 12/31/2010
$24.10	0.4%	01/01/2011 – 12/31/2011
$24.24	0.6%	01/01/2012 – 12/31/2012
$24.43	0.8%	01/01/2013 – 12/31/2013
$24.63	0.8%	01/01/2014 – 12/31/2014
$24.83	0.8%	01/01/2015 – 12/31/2015

F. Valuing New, Revised and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since inception of the PFS, it has also been a priority to revalue services regularly to 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 RVUs for CY 1997, CY 2002, CY 2007, and CY 2012. 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, such as codes with high growth rates, codes that are frequently billed together, and high expenditure codes. Section 3134 of the Affordable Care Act codified the misvalued code initiative in section 1848(c)(2)(K) of the Act.

In the CY 2012 rulemaking process, we proposed and finalized consolidation of the five-year review and the potentially misvalued code activities into an annual review of potentially misvalued codes to avoid redundancies in these efforts and better accomplish our goal of assuring regular assessment of code values. Under the consolidated process, we issue interim final RVUs for all revaluations and new codes in the PFS final rule with comment period, and make payment based upon those values during the calendar year covered by the final rule. (Changes in the PFS methodology that may affect valuations of a variety of codes are issued as proposals in the proposed rule.) We consider and respond to any public comments on the interim final values in the final rule with comment period for the subsequent year. When consolidating these processes, we indicated that it was appropriate to establish interim values for new, revised, and potentially misvalued codes because of the incongruity between the PFS rulemaking cycle and the release of codes by the AMA CPT Editorial Panel and the RUC review process. We

stated that if we did not establish interim final values for revalued codes in the final rule with comment period, "a delay in implementing revised values for codes that have been identified as misvalued would perpetuate payment for the services at a rate that does not appropriately reflect the relative resources involved in furnishing the service and would continue unwarranted distortion in the payment for other services across the PFS." We also reiterated that if we did not establish interim final values for new and revised codes, we would either have to delay the use of new and revised codes for one year, or permit each Medicare contractor to establish its own payment rate for these codes. We stated, "We believe it would be contrary to the public interest to delay adopting values for new and revised codes for the initial year, especially since we have an opportunity to receive significant input from the medical community [through the RUC] before adopting the values, and the alternatives could produce undesirable levels of uncertainty and inconsistency in payment for a year."

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

Under the process finalized in the CY 2012 PFS final rule with comment period, in each year's proposed rule, we propose specific codes and/or groups of codes that we believe may be appropriate to consider under our potentially misvalued code initiative. As part of our process for developing the list of proposed potentially misvalued codes, we consider public nominations for potentially misvalued codes under a process also established in the CY 2012 PFS final rule with comment period. If appropriate, we include such codes in our proposed potentially misvalued code list. In the proposed rule, we solicit comments on the proposed potentially misvalued codes. We then respond to comments and establish a final list of potentially misvalued codes in the final rule for that year. These potentially misvalued codes are reviewed and revalued, if appropriate, in subsequent years. In addition, the RUC regularly identifies

potentially misvalued codes using screens that have previously been identified by CMS, such as codes performed together more than 75 percent of the time.

Generally, the first step in revaluing codes that have been identified as potentially misvalued is for the RUC to review these codes through its standard process, which includes active involvement of national specialty societies for the specialties that ordinarily use the codes. Frequently, the RUC's discussion of potentially misvalued codes will lead the CPT Editorial Panel to make adjustments to the codes involved, such as bundling of codes, creation of new codes or revisions of code descriptors. The AMA has estimated that 75 percent of all annual CPT coding changes result from the potentially misvalued code initiative.

The RUC provides CMS with recommendations for the work values and direct PE inputs for the codes we have identified as potentially misvalued codes or, in the case of a coding revision, for the new or revised codes that will replace these potentially misvalued codes. (This process is also applied to codes that the RUC identifies using code screens that we have identified, and to new or revised codes that are issued for reasons unrelated to the potentially misvalued code process.) Generally, we receive the RUC recommendations concurrently for all codes in the same family as the potentially misvalued code(s). We believe it is important to evaluate and establish appropriate work and MP RVUs and direct PE inputs for an entire code family at the same time to avoid rank order anomalies and to maintain appropriate relativity among codes. We generally receive the RUC recommendations for the code or replacement code(s) within a year or two following the identification of the code as potentially misvalued.

We consider the RUC recommendations along with other information that we have, including information submitted by other stakeholders, and establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there are coding changes in the final rule with comment period for a year. There is a 60–day period for the public to

comment on those interim final values after we issue the final rule. 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. 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.

As we discussed in the CY 2012 PFS final rule with comment period, we adopted this consolidated review process to combine all coding revaluations into one annual process allowing for appropriate consideration of relativity in and across code families. In addition, this process assures that we have the benefit of the RUC recommendations for all codes being valued.

2. Concerns with Current Process.

Some stakeholders who have experienced reductions in payments as the result of interim final valuations have objected to the process by which we revise or establish values for new, revised, and potentially misvalued codes. Some have stated that they did not receive notice of the possible reductions before they occurred. Generally, stakeholders are aware that we are considering changes in the payment rates for particular services either because CPT has made changes to codes or because we have identified the codes as potentially misvalued. As the RUC considers the appropriate value for a service, representatives of the specialties that use the codes are involved in the process. The RUC usually surveys physicians or other practitioners who furnish the services described by the codes regarding the time it takes to furnish the services, and representatives of the specialty(ies) also participate in the RUC meetings where recommendations for work RVUs and direct PE inputs are considered. Through this process, representatives of the affected specialties are generally aware of the RUC recommendations.

Some stakeholders have stated that even when they are aware that the RUC has made recommendations, they have no opportunity to respond to the RUC recommendations before we consider them in adopting interim final values because the RUC actions and recommendations are not public. Some stakeholders have also said that the individuals who participate in the RUC review process are not able to share the recommendations because they have signed a confidentiality agreement. We note, however, that at least one specialty society has raised funds via its website to fight a "pending cut" based upon its knowledge of RUC recommendations for specific codes prior to CMS action on the recommendation. Additionally, some stakeholders have pointed out that some types of suppliers that are paid under the PFS are not permitted to participate in the RUC process at all.

We recognize that some stakeholders, including those practitioners represented by societies that are not participants in the RUC process, may not be aware of the specifics of the RUC recommendations before we consider them in establishing interim final values for new, revised, and potentially misvalued codes. We note that, as described above, before we review a service as a potentially misvalued code, we go through notice and comment rulemaking to identify it as a potentially misvalued code. Thus, the public has notice and an opportunity to comment on whether we should review the values for a code before we finalize the code as potentially misvalued and begin the valuation process. As a result, all stakeholders should be aware that a particular code is being considered as potentially misvalued and that we may establish revised interim final values in a subsequent final rule with comment period. As noted above, there may be some codes for which we receive RUC recommendations based upon their identification by the RUC through code screens that we establish. These codes are not specifically identified by CMS through notice and comment rulemaking as potentially misvalued codes. We recognize that if stakeholders are not monitoring RUC activities or evaluating

Medicare claims data, they may be unaware that these codes are being reviewed and could be revalued on an interim final basis in a final rule with comment period for a year.

In recent years, we have increased our scrutiny of the RUC recommendations and have increasingly found cause to modify the values recommended by the RUC in establishing interim final values under the PFS. Sometimes we also find it appropriate, on an interim final basis, to refine how the CPT codes are to be used for Medicare services or to create G-codes for reporting certain services to Medicare. Some stakeholders have objected to such interim final decisions because they do not learn of the CMS action until the final rule with comment period is issued. Stakeholders said that they do not have an opportunity to meaningfully comment and for CMS to address their comments before the coding or valuation decision takes effect.

We received comments on the CY 2014 PFS final rule with comment period suggesting that the existing process for review and adoption of interim final values for new, revised, and misvalued codes violates section 1871(a)(2) of the Act, which prescribes the rulemaking requirements for the agency in establishing payment rates. In response to those commenters, we note that the process we use to establish interim final rates is in full accordance with the statute and we do not find this a persuasive reason to consider modifying the process that we use to establish PFS rates.

Our recent revaluation of the four epidural injection codes provides an example of the concerns that have been expressed with the existing process. In the CY 2014 PFS final rule with comment period, we established interim final values for four epidural injection codes, which resulted in payment reductions for the services when furnished in the office setting of between 35 percent and 56 percent. (In the facility setting, the reductions ranged from 17 percent to 33 percent.) One of these codes had been identified as a potentially misvalued code 2 years earlier. The affected specialties had been involved in the RUC process and were generally aware that the

family of codes would be revalued on an interim basis in an upcoming rule. They were also aware that the RUC had made significant changes to the direct PE inputs, including removal of the radiographic-fluoroscopy room, which explains, in large part, the reduction to values in the office setting. The societies representing the affected specialty were also aware of significant reductions in the RUC-recommended "time" to furnish the procedures based on the most recent survey of practitioners who furnish the services, which resulted in reductions in both the work and PE portion of the values. Although the specialties were aware of the changes that the RUC was recommending to direct PE inputs, they were not specifically aware of how those changes would affect the values and payment rate. In addition, we decreased the work RVUs for these procedures because we found the RUC-recommended work RVUs did not adequately reflect the RUC-recommended decreases in time. This decision is consistent with our general practice when the best available information shows that the time involved in furnishing the service has decreased, and in the absence of information suggesting an increase in work intensity. Since the interim final values for these codes were issued in the CY 2014 PFS final rule with comment period, we have received numerous comments that will be useful to us as we consider finalizing values for these codes. If we had followed a process that involved proposing values for these codes in a proposed rule, we would have been able to consider the additional information contained in these comments prior to making payments for the services based upon revised values. (See section II.B.3.b.(2) of this final rule with comment period for a discussion of proposed valuation of these epidural injection codes for CY 2015.)

3. Alternatives to the Current Process

In the proposed rule, we noted that given our heightened review of the RUC recommendations and the increased concerns expressed by some stakeholders, we believed that an assessment of our process for valuing these codes was warranted. To that end, we considered

potential alternatives to address the timing and rulemaking issues associated with establishing values for new, revised and potentially misvalued codes (as well as for codes within the same families as these codes). Specifically, we explored three alternatives to our current approach:

- Propose work and MP RVUs and direct PE inputs for all new, revised and potentially misvalued codes in a proposed rule.
- Propose changes in work and MP RVUs and direct PE inputs in the proposed rule for new, revised, and potentially misvalued codes for which we receive RUC recommendations in time; continue to establish interim final values in the final rule for other new, revised, and potentially misvalued codes.
- Increase our efforts to make available more information about the specific issues being considered in the course of developing values for new, revised and potentially misvalued codes to increase transparency, but without making changes to the existing process for establishing values.

In the proposed rule we discussed each of these alternatives as follows.

(a) Propose work and MP RVUs and direct PE inputs for new, revised, and potentially misvalued codes in the proposed rule:

Under this approach, we stated that we would evaluate the RUC recommendations for all new, revised, and potentially misvalued codes, and include proposed work and MP RVUs and direct PE inputs for the codes in the first available PFS proposed rule. We would receive and consider public comments on those proposals and establish final values in the final rule. The primary obstacle to this approach relates to the current timing of the CPT coding changes and RUC activities. Under the current calendar, all CPT coding changes and most RUC recommendations are not available to us in time to include proposed values for all codes in the proposed rule for that year.

Therefore, we stated that if we were to adopt this proposal, which would require us to propose changes in inputs before we revalue codes based upon those values, we would need a mechanism to pay for services for which the existing codes would no longer be available, or for which there would be changes for a given year.

As we noted in the CY 2012 PFS final rule with comment period, the RUC recommendations are an essential element that we consider when valuing codes. Likewise, we recognize the significant contribution that the CPT Editorial Panel makes to the success of the potentially misvalued code initiative through its consideration and adoption of coding changes. Although we have increased our scrutiny of the RUC recommendations in recent years and accepted fewer of the recommendations without making our own refinements, the CPT codes and the RUC recommendations continue to play a major role in our valuations. For many codes, the surveys conducted by specialty societies as part of the RUC process are the best data that we have regarding the time and intensity of work. The RUC determines the criteria and the methodology for those surveys. It also reviews the survey results. This process allows for development of survey data that are more reliable and comparable across specialties and services than would be possible without having the RUC at the center of the survey vetting process. In addition, the debate and discussion of the services at the RUC meetings in which CMS staff participate provides a good understanding of what the service entails and how it compares to other services in the family, and to services furnished by other specialties. The debate among the specialties is also an important part of this process. Although we increasingly consider data and information from many other sources, and we intend to expand the scope of those data and sources, the RUC recommendations remain a vital part of our valuation process.

Thus, if we were to adopt this approach, we would need to address how to make payment for the services for which new or revised codes take effect for the following year but for which

we did not receive RUC recommendations in time to include proposed work values and PE inputs in the proposed rule. Because the annual coding changes are effective on January 1st of each year, we would need a mechanism for practitioners to report services and be paid appropriately during the interval between the date the code takes effect and the time that we receive RUC recommendations and complete rulemaking to establish values for the new and revised codes. One option would be to establish G-codes with identical descriptors to the predecessors of the new and revised codes and, to the fullest extent possible, carry over the existing values for those codes. This would effectively preserve the status quo for one year.

The primary advantage of this approach would be that the RVUs for all services under the PFS would be established using a full notice and comment procedure, including consideration of the RUC recommendations, before they take effect. In addition to having the benefit of the RUC recommendations, this would provide the public the opportunity to comment on a specific proposal prior to it being implemented. This would be a far more transparent process, and would assure that we have the full benefit of stakeholder comments before establishing values.

One drawback to such a process is that the use of G-codes for a significant number of codes may create an administrative burden for CMS and for practitioners. Presumably, practitioners would need to use the G-codes to report certain services for purposes of Medicare, but would use the new or revised CPT codes to report the same services to private insurers. The number of G-codes needed each year would depend on the number of CPT code changes for which we do not receive the RUC recommendations in time to formulate a proposal to be included in the proposed rule for the year. To the extent that we receive the RUC recommendations for all new and revised codes in time to develop proposed values for inclusion in the proposed rule, there would be no need to use G-codes for this purpose.

Another drawback is that we would need to delay for at least one year the revision of values for any misvalued codes for which we do not receive RUC recommendations in time to include a proposal in the proposed rule. For a select set of codes, we would be continuing to use the RVUs for the codes for an additional year even though we know they do not reflect the most accurate resources. Since the PFS is a budget neutral system, misvalued services affect payments for all services across the fee schedule. On the other hand, if we were to take this approach, we would have the full benefit of public comments received on the proposed values for potentially misvalued services before implementing any revisions.

(b) Propose changes in work and MP RVUs and PE inputs in the proposed rule for new, revised, and potentially misvalued codes for which we receive RUC recommendations in time; continue to establish interim final values in the final rule for other new, revised, and potentially misvalued codes:

This alternative approach would allow for notice and comment rulemaking before we adopt values for some new, revised and potentially misvalued codes (those for which we receive RUC recommendations in time to include a proposal in the proposed rule), while others would be valued on an interim final basis (those for which we do not receive the RUC recommendations in time). Under this approach, we would establish values in a year for all new, revised, and potentially misvalued codes, and there would be no need to provide for a mechanism to continue payment for outdated codes pending receipt of the RUC recommendations and completion of a rulemaking cycle. For codes for which we do not receive the RUC recommendations in time to include a proposal in the proposed rule for a year, there would be no change from the existing valuation process.

This would be a balanced approach that recognizes the benefits of a full opportunity for notice and comment rulemaking before establishing rates when timing allows, and the

importance of establishing appropriate values for the current version of CPT codes and for potentially misvalued codes when the timing of the RUC recommendations does not allow for a full notice and comment procedure.

However, this alternative would go only part of the way toward addressing concerns expressed by some stakeholders. For those codes for which the RUC recommendations are not received in time for us to include a proposal in the proposed rule, Medicare payment for one year would still be based on inputs established without the benefit of full public notice and comment. Another concern with this approach is that it could lead to the valuation of codes within the same family at different times depending on when we receive RUC recommendations for each code within a family. As discussed previously, we believe it is important to value an entire code family together to make adjustments to account appropriately for relativity within the family and between the family and other families. If we receive RUC recommendations in time to propose values for some, but not for all, codes within a family, we would respond to comments in the final rule to establish final values for some of the codes while adopting interim final values for other codes within the same family. The differences in the treatment of codes within the same family could limit our ability to value codes within the same family with appropriate relativity. Moreover, under this alternative, the main determinant of how a code would be handled would be the timing of our receipt of the RUC recommendation for the code. Although this approach would offer stakeholders the opportunity to comment on specific proposals in the proposed rule, the adoption of changes for a separate group of codes in the final rule could significantly change the proposed values simply due to the budget neutrality adjustments due to additional codes being valued in the final rule.

(c) <u>Increase our efforts to make available more information about the specific issues being considered in the course of developing values for new, revised and potentially misvalued</u>

codes in order to increase transparency, but without a change to the existing process for establishing values:

The main concern with continuing our current approach is that stakeholders have expressed the desire to have adequate and timely information to permit the provision of relevant feedback to CMS for our consideration prior to establishing a payment rate for new, revised, and potentially misvalued codes. We could address some aspects of this issue by increasing the transparency of the current process. Specifically, we could make more information available on the CMS website before interim final values are established for codes. Examples of such information include an up-to-date list of all codes that have been identified as potentially misvalued, a list of all codes for which RUC recommendations have been received, and the RUC recommendations for all codes for which we have received them.

Although the posting of this information would significantly increase transparency for all stakeholders, it still would not allow for full notice and comment rulemaking procedures before values are established for payment purposes. Nor would it provide the public with advance information about whether or how we will make refinements to the RUC recommendations or coding decisions in the final rule with comment period. Thus, stakeholders would not have an opportunity to provide input on our potential modifications before interim final values are adopted.

4. Proposal to Modify the Process for Establishing Values for New, Revised, and Potentially Misvalued Codes.

After considering the current process, including its strengths and weaknesses, and the alternatives to the current process described previously, we proposed to modify our process to make all changes in the work and MP RVUs and the direct PE inputs for new, revised and potentially misvalued services under the PFS by proposing the changes in the proposed rule,

beginning with the PFS proposed rule for CY 2016. We proposed to include proposed values for all new, revised and potentially misvalued codes for which we have complete RUC recommendations by January 15th of the preceding year. We also proposed to delay revaluing the code for one year (or until we receive RUC recommendations for the code before January 15th of a year) and include proposed values in the following year's rule if the RUC recommendation was not received in time for inclusion in the proposed rule. Thus, we would include proposed values prior to using the new code (in the case of new or revised codes) or revising the value (in the case of potentially misvalued codes). Due to the complexities involved in code changes and rate setting, there could be some circumstances where, even when we receive the RUC recommendations by January 15th of a year, we are not able to propose values in that year's proposed rule. For example, we might not have recommendations for the whole family or we might need additional information to appropriately value these codes. In situations where it would not be appropriate or possible to propose values for certain new, revised, or potentially misvalued codes, we would treat them in the same way as those for which we did not receive recommendations before January 15th.

For new, revised, and potentially misvalued codes for which we do not receive RUC recommendations before January 15th of a year, we proposed to adopt coding policies and payment rates that conform, to the extent possible, to the policies and rates in place for the previous year. We would adopt these conforming policies on an interim basis pending our consideration of the RUC recommendations and the completion of notice and comment rulemaking to establish values for the codes. For codes for which there is no change in the CPT code, it is a simple matter to continue the current valuation. For services for which there are CPT coding changes, it is more complicated to maintain the current payment rates until the codes can be valued through the notice and comment rulemaking process. Since the changes in CPT

codes are effective on January 1st of a year, and we would not have established values for the new or revised codes (or other codes within the code family), it would not be practical for Medicare to use those CPT codes. For codes that were revised or deleted as part of the annual CPT coding changes, when the changes could affect the value of a code and we have not had an opportunity to consider the relevant RUC recommendations prior to the proposed rule, we propose to create G-codes to describe the predecessor codes to these codes. If CPT codes are revised in a manner that would not affect the resource inputs used to value the service (for example, a grammatical changes to CPT code descriptors), we could use these revised codes and continue to pay at the rate developed through the use of the same resource inputs. For example, if a single CPT code was separated into two codes and we did not receive RUC recommendations for the two codes before January 15th of the year, we would assign each of those new codes an "I" status indicator (which denotes that the codes are "not valid for Medicare purposes"), and those codes could not be used for Medicare payment during the year. Instead, we would create a G-code with the same description as the single predecessor CPT code and continue to use the same inputs as the predecessor CPT code for that G-code during the year.

For new codes that describe wholly new services, as opposed to new or revised codes that are created as part of a coding revision of a family or that describe services are already on the PFS, we would make every effort to work with the RUC to ensure that we receive recommendations in time to include proposed values in the proposed rule. However, if we do not receive timely recommendations from the RUC for such a code and we determine that it is in the public interest for Medicare to use a new code during the code's initial year, we would establish values for the code's initial year. As we do under our current policy, if we receive the RUC recommendations in time to consider them for the final rule, we propose to establish values for the initial year on an interim final basis subject to comment in the final rule. In the event we

do not receive RUC recommendations in time to consider them for the final rule, or in other situations where it would not be appropriate to establish interim final values (for example, because of a lack of necessary information about the work or the price of the PE inputs involved), we would contractor price the code for the initial year.

We specifically sought comments on the following topics:

- Is this proposal preferable to the present process? Is another one of the alternatives better?

- If we were to implement this proposal, is it better to move forward with the changes, or is more time needed to make the transition such that implementation should be delayed beyond CY 2016? What factors should we consider in selecting an implementation date?

- Are there alternatives other than the use of G-codes that would allow us to address the annual CPT changes through notice and comment rather than interim final rulemaking?

Comment: The vast majority of commenters support a process, such as the one we proposed, that would result in having an opportunity for public comment on specific CMS proposals to change rates prior to payments being made based upon those rates. Commenters supporting a more transparent process include most medical organizations. MedPAC supported including proposals for rate changes in the proposed rule, but disagreed with preserving existing rates when RUC recommendations were not received in time to value in the proposed rule stating that this perpetuates paying at rates that we know are misvalued. As an alternative, MedPAC suggested that for codes for which we received RUC recommendations after the deadline for the proposed rule, we establish interim final values using the existing process. MedPAC also encouraged us to work with the CPT Editorial Panel and the RUC to better disseminate information about coding and payment recommendations that might be used for interim values as far in advance as possible. Several commenters who do not currently participate in the

development of RUC recommendations suggested that we require the RUC to make its operations more transparent. Most of the commenters that supported the proposal also suggested making at least some modifications to the proposal. Some commenters indicated there was no need for a change from the current process. Another commenter stated "CMS's proposal is overly complex, potentially burdensome, and goes well beyond the principal request of the medical specialty societies and Congress – that is, for CMS to publish reimbursement changes for misvalued codes in the proposed rule, as opposed to waiting until the final rule."

Response: We appreciate the many comments in support of our proposal to be more transparent in our ratesetting process by including proposed changes in inputs for new, revised, and potentially misvalued codes in the PFS proposed rules each year. We received only minimal comments on the other alternatives we presented, and only one comment suggesting that the current process was ideal and should be maintained. Thus, we are finalizing the proposal, with the modifications discussed below, to change our process for establishing values for new, revised, and potentially misvalued codes each year by proposing values for them in the proposed rule. We note that the CPT Editorial Panel and the RUC have made significant efforts in recent years to make their processes more transparent, such as making minutes of meetings publicly available. We encourage them to continue these efforts and also to consider ways that all physicians, practitioners and other suppliers paid under the PFS are aware of issues that are being considered by the RUC, and have an opportunity to provide input. With regard to comments suggesting that we propose values for some codes in the proposed rule and establish values for others as interim final in the final rule with comment period, as we discussed in making the proposal, we believe this type of system has several flaws. Most significantly, since the PFS is a budget neutral system, proposals are more meaningful when they can be considered in relation to all codes being revalued in a year in order to allow public comment on the entire fee schedule at

one time. Additionally, we believe it is difficult to justify the presence or absence of an opportunity for public comment in advance of our adopting and using new values and inputs for services when the outcome essentially depends upon when we receive RUC recommendations.

Comment: Commenters expressed mixed opinions on when the new process should begin. The AMA, the RUC, and most medical specialties opposed the proposed CY 2016 implementation and asked that it be delayed until CY 2017. Commenters supporting a delay suggested that much work had already been done for the CY 2016 coding cycle in anticipation that these codes could be used for CY 2016, and stated it seems unfair to now delay valuing these codes because the process is being changed. These commenters also suggested that by delaying until CY 2017, the CPT Editorial Panel and the RUC would have time to adjust their agendas and workload so as to provide more recommendations in time for the proposed rule. By contrast, several commenters, including those with major code revisions for CY 2015, such as codes for radiation therapy and upper gastrointestinal procedures, suggested that we should implement the new process immediately, and thus, delay implementation of the new code sets and values so that they could be issued as proposals in the CY 2016 proposed rule. Although each of the commenters took some unique positions in supporting a delay, they emphasized the importance of the opportunity to comment on our specific proposals for valuation as a major consideration for the delay. A few other commenters also suggested that the benefit of the opportunity for public comment prior to changing values warrants immediate implementation. Some commenters supported a CY 2016 implementation date as we proposed. A small group of commenters suggested an interim approach under which, for CY 2016, we would publish "some, but not all, values" in the proposed rule and use the interim final approach for others.

Response: After reviewing the comments, we understand that the implementation of a new process such as this one will affect stakeholders in differing ways. As we consider the most

appropriate time frame for implementation, we believe that flexibility in implementation offers the optimal solution. Accordingly, we are delaying the adoption of two new codes sets (radiation therapy and lower gastrointestinal endoscopies) until CY 2016 as requested by affected stakeholders so that those most affected by these significant changes have the opportunity to comment on our proposals for valuing these codes sets before they are implemented. (See section II.G.3 of this final rule.)

Similarly, as requested by the AMA and most other medical specialty societies, we are delaying the complete implementation of this process so that those who have requested new codes and modifications in existing codes with the expectation that they would be valued under the PFS for CY 2016 will not be negatively affected by timing of this change. We note that the AMA has been working to develop timeframes that would allow a much higher percentage of codes to be addressed in the proposed rule, and has shared with us some plans to achieve this goal. We appreciate AMA's efforts and are confident that with the finalization of this process, the CPT Editorial Panel and the RUC will be able to adjust their timelines and processes so that most, if not all, of the annual coding changes and valuation recommendations can be addressed in the proposed rule prior to the effective date of the coding changes. This delay in implementation will provide additional time for these bodies to adjust their agendas and the timing of their recommendations to CMS to more appropriately align with the new process. As suggested by some commenters, we will use CY 2016 as a transition year. In the PFS proposed rule for CY 2016, we will propose values for the new, revised and potentially misvalued codes for which we receive the RUC recommendations in time for inclusion in the CY 2016 proposed rule. We will also include proposals for the two code sets delayed from CY 2015 in the CY 2016 proposed rule, as discussed above. For those new, revised, and potentially misvalued codes for which we do not receive RUC recommendations in time for inclusion in the proposed rule, we

anticipate establishing interim final values for them for CY 2016, consistent with the current process. Beginning with valuations for CY 2017, the new process will be applicable to all codes. In other words, 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 certain 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. Consistent with this policy, we are finalizing our proposed regulatory change to §414.24 with the addition of the phrase "For valuations for calendar year 2017 and beyond," to paragraph (b) to reflect the implementation for all CY 2017 valuations."

Comment: Commenters also addressed the January 15th deadline for valuations to be considered for the proposed rule. The AMA recommended a deadline of 30 days after the RUC's January meeting to allow time to submit complete recommendations for the proposed rule. Many others supported this, with some commenters suggesting a variety of dates between January 31st and April. Commenters suggested using an April deadline so that we could include the recommendations from the April RUC meeting in the proposed rule.

Response: In proposing a deadline for inclusion in the proposed rule, we attempted to strike a balance that allows CMS adequate time for CMS to do a thorough job in vetting recommendations and formulating proposals, and allows the RUC as much time as possible to complete its activities. Review of RUC recommendations and application of the PFS methodology to particular codes requires significant time to complete. With new statutory requirements being implemented in CY 2017, such as those requiring multi-year transitions of certain changes in values and modification to PFS payments if specified targets are not met, we

believe we will need more time to complete the process of formulating proposals. We believe that we need to establish a consistent deadline for receipt of RUC recommendations in order to allow all stakeholders and CMS to plan appropriately. To balance competing priorities, we are finalizing a deadline of February 10th. Our ability to complete our work in this more limited time will depend in large part on the volume of recommendations handled at the last RUC meeting and when we receive those recommendations. We are seeking the RUC's assistance in minimizing the recommendations that we receive after the beginning of the year.

Comment: The majority of commenters opposed the use of G-codes, primarily citing the administrative burden of having to use a separate set of codes for Medicare claims. One commenter called the G-code proposal "unworkable." In addition, MedPAC objected to the principal of attempting to maintain rates that are known to be misvalued. Those supporting the use of G-codes generally recognized the administrative burden, but believed the importance of the opportunity for public comment on proposed values before they take effect outweighed the administrative inconvenience. Commenters urged us to minimize the use of G-codes.

Response: We recognize the commenters' concerns with the use of G-codes. We agree that it is preferable to use CPT codes whenever possible. Under our finalized process, the use of G-codes for the purpose of holding over current coding and payment policies should not be necessary, generally, as long as we receive RUC recommendations for all new, revised and potentially misvalued codes before February 10th of the prior year. However, we need to preserve our ability to establish a proxy for current coding and values in situations where we receive the RUC recommendations too late or, for some other reason, encounter serious difficulty developing proposed values for revised code sets. In the proposed rule, we sought input as to ways to achieve this without using G-codes. The only suggestion offered by commenters was to value such codes on an interim final basis. As we discuss above, we believe

the program and its stakeholders are better served by delaying revaluations for one year while we used the notice and comment process to obtain public comments in advance. The comments on this proposal were overall overwhelming supportive of this point of view. Accordingly, we are not foreclosing the possibility of using G-codes for this purpose when warranted by the circumstances. However, we are cognizant of the difficulties created by the use of G-codes and will seek to minimize their use. We also note that the RUC and stakeholders can assist us in minimizing the use of G-codes by taking steps to insure that we receive RUC recommendations as early as possible.

5. Refinement Panel.

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be comprised 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 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.

As we considered making changes to the process for valuing codes, 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 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. We noted that if our proposal to modify the valuation process for new, revised, and potentially misvalued codes is adopted, there would no longer be interim final values except for very few codes that describe totally new services. Thus, we proposed eliminating the refinement panel process.

We also noted that by using the proposed process for new, revised, and potentially misvalued codes, we believed the consideration of additional clinical information and any other issues associated with the CMS proposed values could be addressed through the notice and comment process. Similarly, prior to CY 2012 when we consolidated the five-year valuation, changes made as part of the five-year review process were addressed in the proposed rule and those codes were generally not subject to the refinement process. The notice and comment process would provide stakeholders with complete information on the basis and rationale for our proposed inputs and any relating coding policies. We also noted that an increasing number of requests for refinement do not include new clinical information that would justify a change in the work RVUs and that was not available at the time of the RUC meeting, in accordance with the current criteria for refinement. Thus, we did not believe the elimination of the refinement panel process would negatively affect the code valuation process. We believe the proposed process, which includes a full notice and comment procedure before values are used for purposes of payment, offers stakeholders a better mechanism for providing any additional data for our consideration and discussing any concerns with our proposed values than the current refinement process

Comment: We received many comments on our proposal to eliminate the refinement panel, but most addressed problems with the existing refinement process and suggested improvements and alternatives rather than reasons not to eliminate the refinement panel. Concerns with the refinement panel process included that CMS imposed too high a standard for referring codes to refinement and that CMS decreasingly changed values based upon the refinement panel results. Some noted that organizations with limited resources are disadvantaged compared to those with significant resources to overturn any CMS interim final values without a refinement process. In addition, some commenters stated that elimination of the refinement panel runs contrary to the transparency that CMS is trying to achieve. Many discussed their previous understanding that the refinement panel was essentially an appeals process for interim final values.

Commenters supported "a fair, objective, and consistently applied appeals process that would be open to any commenting organization." Commenters expressed concern that the elimination of the refinement panel without a replacement mechanism "indicates that CMS will no longer seek the independent advice of contractor medical officers and practicing physicians and will solely rely on Agency staff to determine if the comment is persuasive in modifying a proposed value. The lack of any perceived organized appeal process will likely lead to a fragmented lobbying effort, rather than an objective review process."

MedPAC suggested that we use a panel with membership limited to those without a financial stake in the process, such as contractor medical directors, experts in medical economics and technology diffusion, private payer representatives, and a mix of physicians and other health professionals not directly affected by the RVUs in question. It also suggested user fees to provide the resources needed or such a refinement panel.

Response: We acknowledge the commenters' concerns and believe that some of the

dissatisfaction with the current refinement panel mechanism stems from the expectation that it constitutes an appeals process. We do not agree. We believe the purpose of the refinement panel is to give us additional information to consider in exercising our responsibility to establish appropriate RVUs for Medicare services. Like many of the commenters, we believe the refinement panel is not achieving its purpose. Rather than providing us with additional information to assist us in establishing work RVUs, most often the refinement panel discussion reiterates the issues raised and information discussed at the RUC. Since we had access to this information at the time interim final values were established, it seems unlikely that a repeat discussion of the same issues would lead us to change valuations based upon information that already had been carefully considered. We remain concerned about the amount of resources devoted to refinement panel activities as compared to the benefit received. However, in light of the significant concerns raised by commenters, we are not finalizing our proposal to eliminate the refinement panel. We will use the refinement panel for consideration of interim final rates for CY 2015 under the existing rules. We will also explore ways to address the many concerns that we and stakeholders have about the refinement panel process and whether the change in process eliminates the need for a refinement panel.

We are also finalizing our proposed change to the regulation at §414.24 with the addition of the phrase "For valuations for calendar year 2017 and beyond," to paragraph (b) to reflect implementation of the revised process for all valuations beginning with those for CY 2017.

G. Establishing RVUs for CY 2015

1. Methodology

We conducted a review of each code identified in this section and reviewed the current work RVU, if one exists, the RUC-recommended work RVUs, intensity, and time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review generally includes, but is not limited to, a review of information provided by the RUC, Health Care Professionals Advisory Committee (HCPAC), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government. 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 components could be the CPT codes that make up the bundled code. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician

work for that service relative to the physician work for similar service across the PFS without explicitly valuing the components of that work.

The PFS incorporates cross-specialty and cross-organ system relativity. Valuing services requires an assessment of relative value and takes into account the clinical intensity and time required to furnish a service. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services.

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

We have developed several standard building block methodologies to appropriately value services when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. We believe that at least one-third of the physician time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the

product of the time involved in furnishing the service times the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU. Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes × 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

The RVUs and other payment information for all CY 2015 payable codes are available in Addendum B. The RVUs and other payment information for all codes subject to public comment are available in Addendum C. Both addenda are available on the CMS website under downloads for the CY 2015 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/downloads/. The time values for all CY 2015 codes are listed in a file called "CY 2015 PFS Physician Time," available on the CMS website under downloads for the CY 2015 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/downloads/.

2. Addressing CY 2014 Interim Final RVUs

In this section, we are responding to the public comments received on specific interim final values established in the CY 2014 PFS final rule with comment period and discussing the final values that we are establishing for CY 2015. The final CY 2015 work, PE, and MP RVUs are in Addendum B of a file called "CY 2015 PFS Addenda," available on the CMS website under downloads for the CY 2015 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/PFS-Federal-Regulation-Notices.html/. The direct PE

inputs are listed in a file called "CY 2015 PFS Direct PE Inputs," available on the CMS website under downloads for the CY 2015 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/PFS-Federal-Regulation-Notices.html/.

a. Finalizing CY 2014 Interim Final Work RVUs for CY 2015

(i) Refinement Panel

(1) Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process soon after implementing the fee schedule to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in developing final work values for the subsequent year. We decided the panel would be comprised 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 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. Depending on the number and range of codes that are subject to refinement in a given year, we establish refinement panels with representatives from four groups: Clinicians representing the specialty identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typical panels have included 8 to 10 physicians across the four groups.

Following the addition of section 1848(c)(2)(K) to the Act, which requires the Secretary periodically to 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 believed that the refinement panel process might

provide an opportunity to review and discuss the proposed and interim final work RVUs with a clinically diverse group of experts, who could provide informed recommendations following the discussion. Therefore, we indicated that we would continue the refinement process, but with administrative modification and clarification. We also noted that we would continue using the established panel composition that includes representatives from the four groups—clinicians representing the specialty identified with the procedures in question, physicians with practices in related specialties, primary care physicians, and CMDs.

At that time, we made a change in how we calculated refinement panel results. The basis of the refinement panel process is that, following discussion of the information but without an attempt to reach a consensus, each member of the panel submits an independent rating to CMS. Historically, the refinement panel's recommendation to change a work value or to retain the interim final value had hinged solely on the outcome of a statistical test on the ratings (an F-test of panel ratings among the groups of participants). Over time, we found the statistical test used to evaluate the RVU ratings of individual panel members became less reliable as the physicians in each group tended to select a previously discussed value, rather than developing a unique value, thereby reducing the observed variability needed to conduct a robust statistical test. In addition, reliance on values developed using the F-test also occasionally resulted in rank order anomalies among services (that is, a more complex procedure is assigned lower RVUs than a less complex procedure). As a result, we eliminated the use of the statistical F-test and replaced it with the median work value of the individual panel members' ratings. We stated that this approach would simplify the refinement process administratively, while providing a result that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values. We also clarified that we have the final authority to set the work RVUs, including making adjustments to the work RVUs

resulting from the refinement process, and that we will make such adjustments if warranted by policy concerns (75 FR 73307).

We remind readers that the refinement panels are not intended to review the work RVUs for every code for which we did not accept the RUC-recommended work RVUs. Rather, refinement panels are designed for situations where there is new clinical information available that might provide a reason for a change in work values and where a multispecialty panel of physicians might provide input that would assist us in establishing work RVUs. To facilitate the selection of services for the refinement panels, commenters seeking consideration by a refinement panel should specifically state in their public comments that they are requesting refinement panel review. Furthermore, we have asked commenters requesting refinement panel review to submit any new clinical information concerning the work required to furnish a service so that we can consider whether the new information warrants referral to the refinement panel (57 FR 55917).

We note that most of the information presented during the last several refinement panel discussions has been duplicative of the information provided to the RUC during its development of recommendations and considered by CMS in establishing values. As detailed above, we consider information and recommendations from the RUC when assigning proposed and interim final RVUs to services. Thus, if the only information that a commenter has to present is information already considered by the RUC, referral to a refinement panel is not appropriate. We request that commenters seeking refinement panel review of work RVUs submit supporting information that has not already been considered by the RUC in developing recommendations or by CMS in assigning proposed and interim final work RVUs. We can make best use of our resources, as well as those of the specialties and physician volunteers involved, by avoiding duplicative consideration of information by the RUC, CMS, and a refinement panel. To achieve

this goal, CMS will continue to critically evaluate the need to refer codes to refinement panels in future years, specifically considering any new information provided by commenters.

(2) CY 2014 Interim Final Work RVUs Considered by the Refinement Panel

We referred to the CY 2014 refinement panel 19 CPT codes with CY 2014 interim final work values for which we received a request for refinement that met the requirements described above. For these 19 CPT codes, all commenters requested increased work RVUs. For ease of discussion, we will be referring to these services as "refinement codes." Consistent with the process described above, we convened a multi-specialty panel of physicians to assist us in the review of the information submitted to support increased work RVUs. The panel was moderated by our physician advisors, and consisted of the following voting members:

- One to two clinicians representing the commenting organization.
- One to two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians.
- Four Contractor Medical Directors (CMDs).
- One to two clinicians with practices in related specialties, who were expected to have knowledge of the services under review.

The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the work of the refinement code(s) and submitted those ratings to CMS directly and confidentially. We note that not all voting participants voted for every CPT code. There was no attempt to achieve consensus among the panel members. As finalized in the CY 2011 PFS final rule with comment period (75 FR 73307), we calculated the median value for each service based upon the individual ratings that were submitted to CMS by panel participants.

Table 14 presents information on the work RVUs for the refinement codes, including the refinement panel ratings and the final CY 2015 work RVUs. In section II.G.2.a.ii., we discuss the CY 2015 work RVUs assigned each of the individual refinement codes.

TABLE 14: Codes Reviewed by the 2014 Multi-Specialty Refinement Panel

HCPCS Code	Descriptor	CY 2014 Interim Final Work RVU	RUC Recommended Work RVU	Refinement Panel Median Rating	CY 2015 Work RVU
19081	Biopsy of breast accessed through the skin with stereotactic guidance	3.29	3.29	3.40	3.29
19082	Biopsy of breast accessed through the skin with stereotactic guidance	1.65	1.65	1.78	1.65
19083	Biopsy of breast accessed through the skin with ultrasound guidance	3.10	3.10	3.10	3.10
19084	Biopsy of breast accessed through the skin with ultrasound guidance	1.55	1.55	1.55	1.55
19085	Biopsy of breast accessed through the skin with MRI guidance	3.64	3.64	3.64	3.64
19086	Biopsy of breast accessed through the skin with MRI guidance	1.82	1.82	1.82	1.82
19281	Placement of breast localization devices accessed through the skin with mammographic guidance	2.00	2.00	2.00	2.00
19282	Placement of breast localization devices accessed through the skin with mammographic guidance	1.00	1.00	1.00	1.00
19283	Placement of breast localization devices accessed through the skin with stereotactic guidance	2.00	2.00	2.00	2.00
19284	Placement of breast localization devices accessed through the skin with stereotactic guidance	1.00	1.00	1.00	1.00
19285	Placement of breast localization devices accessed through the skin with ultrasound guidance	1.70	1.70	1.70	1.70
19286	Placement of breast localization devices accessed through the skin with ultrasound guidance	0.85	0.85	0.85	0.85
19287	Placement of breast localization devices accessed through the skin with MRI guidance	2.55	3.02	3.02	2.55
19288	Placement of breast localization devices accessed through the skin with MRI guidance	1.28	1.51	1.51	1.28
43204	Injection of dilated esophageal veins using an endoscope	2.40	2.89	2.77	2.40
43205	Tying of esophageal veins using an endoscope	2.51	3.00	2.88	2.51
43213	Dilation of esophagus using an endoscope	4.73	5.00	5.00	4.73

HCPCS Code	Descriptor	CY 2014 Interim Final Work RVU	RUC Recommended Work RVU	Refinement Panel Median Rating	CY 2015 Work RVU
43233	Balloon dilation of esophagus, stomach, and/or upper small bowel using an endoscope	4.05	4.45	4.26	4.26
43255	Control of bleeding of esophagus, stomach, and/or upper small bowel using an endoscope	3.66	4.20	4.20	3.66

(ii) Code-Specific Issues

For each code with an interim final work value, Table 15 lists the CY 2014 interim final work RVU and the CY 2015 work RVU and indicates whether we are finalizing the CY 2015 work RVU. For codes without a work RVU, the table includes a PFS procedure status indicator. A list of the PFS procedure status indicators can be found in Addendum A. If the CY 2015 Action column indicates that the CY 2015 values are interim final, we will accept public comments on these values during the public comment period for this final rule with comment period. A comprehensive list of all values for which public comments are being solicited is contained in Addendum C to the CY 2015 PFS final rule with comment period. A comprehensive list of all CY 2015 RVUs is in Addendum B to this final rule with comment period. All Addenda to PFS final rule are available on the CMS website under downloads at http://www.cms.gov/physician feesched/PFS Federal Regulation Notices.html/. The time values for all codes are listed in a file called "CY 2015 PFS Work Time," available on the CMS website under downloads for the CY 2015 PFS final rule with comment period at http://www.cms.gov/physicianfeesched/downloads/.

TABLE 15: CY 2015 Actions on Codes with CY 2014 Interim Final RVUs

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous	3.00	3.00	Finalize
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion	0.61	0.61	Finalize
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (list separately in addition to code for first lesion)	0.04	0.04	Finalize
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions	1.37	1.37	Finalize
17311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks	6.20	6.20	Finalize
17312	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.30	3.30	Finalize
17313	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks	5.56	5.56	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
17314	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.06	3.06	Finalize
17315	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (list separately in addition to code for primary procedure)	0.87	0.87	Finalize
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	3.29	3.29	Finalize
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary procedure)	1.65	1.65	Finalize
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance	3.10	3.10	Finalize
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	1.55	1.55	Finalize
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance	3.64	3.64	Finalize
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	1.82	1.82	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	2.00	2.00	Finalize
19282	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (list separately in addition to code for primary procedure)	1.00	1.00	Finalize
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance	2.00	2.00	Finalize
19284	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary procedure)	1.00	1.00	Finalize
19285	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance	1.70	1.70	Finalize
19286	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	0.85	0.85	Finalize
19287	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance	2.55	2.55	Finalize
19288	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	1.28	1.28	Finalize
23333	Removal of foreign body, shoulder; deep (subfascial or intramuscular)	6.00	6.00	Finalize
23334	Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component	15.50	15.50	Finalize
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	19.00	19.00	Finalize
23600	Closed treatment of proximal humeral (surgical or anatomical neck) fracture; without manipulation	3.00	3.00	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
24160	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and ulnar components	18.63	18.63	Finalize
24164	Removal of prosthesis, includes debridement and synovectomy when performed; radial head	10.00	10.00	Finalize
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	20.72	20.72	Finalize
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	17.61	17.61	Finalize
27446	Arthroplasty, knee, condyle and plateau; medial or lateral compartment	17.48	17.48	Finalize
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	20.72	20.72	Finalize
28470	Closed treatment of metatarsal fracture; without manipulation, each	2.03	2.03	Finalize
29075	Application, cast; elbow to finger (short arm)	0.77	0.77	Finalize
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	0.25	0.25	Finalize
29582	Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed	0.35	0.35	Finalize
29583	Application of multi-layer compression system; upper arm and forearm	0.25	0.25	Finalize
29584	Application of multi-layer compression system; upper arm, forearm, hand, and fingers	0.35	0.35	Finalize
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (mumford procedure)	8.98	8.98	Finalize
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (list separately in addition to code for primary procedure)	3.00	3.00	Finalize
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)	2.60	2.60	Finalize
31238	Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage	2.74	2.74	Finalize
31239	Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy	9.04	9.04	Finalize
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection	2.61	2.61	Finalize
33282	Implantation of patient-activated cardiac event recorder	3.50	3.50	Finalize

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33284	Removal of an implantable, patient-activated cardiac event recorder	3.00	3.00	Finalize
33366	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; transapical exposure (eg, left thoracotomy)	35.88	35.88	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
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

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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
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
35301	Thromboendarterectomy, including patch graft, if performed; carotid, vertebral, subclavian, by neck incision	21.16	21.16	Finalize
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	4.90	4.90	Finalize
37217	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation	20.38	20.38	Finalize
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery	9.00	9.00	Finalize

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37237	Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (list separately in addition to code for primary procedure)	4.25	4.25	Finalize
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein	6.29	6.29	Finalize
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (list separately in addition to code for primary procedure)	2.97	2.97	Finalize
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	9.00	9.00	Finalize
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	10.05	10.05	Finalize
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	11.99	11.99	Finalize
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	14.00	14.00	Finalize
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)	2.00	2.49	Finalize
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance	2.45	2.79	Finalize

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43193	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	3.00	2.79	Finalize
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)	3.00	3.51	Finalize
43195	Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)	3.00	3.07	Finalize
43196	Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire	3.30	3.31	Finalize
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.48	1.52	Finalize
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	1.78	1.82	Finalize
43200	Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.50	1.52	Finalize
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	1.80	1.82	Finalize
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	1.80	1.82	Finalize
43204	Esophagoscopy, flexible, transoral; with injection sclerosis of esophageal varices	2.40	2.43	Finalize
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	2.51	2.54	Finalize
43206	Esophagoscopy, flexible, transoral; with optical endomicroscopy	2.39	2.39	Finalize
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	4.21	4.30	Finalize
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	3.38	3.50	Finalize
43213	Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)	4.73	4.73	Finalize
43214	Esophagoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	3.38	3.50	Finalize
43215	Esophagoscopy, flexible, transoral; with removal of foreign body(s)	2.51	2.54	Finalize
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	2.40	2.40	Finalize
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	2.90	2.90	Finalize

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43220	Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter)	2.10	2.10	Finalize
43226	Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire	2.34	2.34	Finalize
43227	Esophagoscopy, flexible, transoral; with control of bleeding, any method	2.99	2.99	Finalize
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	3.54	3.59	Finalize
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	2.90	2.90	Finalize
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	3.54	3.59	Finalize
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	4.05	4.17	Finalize
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	2.17	2.19	Finalize
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	2.47	2.49	Finalize
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	3.57	3.57	Finalize
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	4.11	4.26	Finalize
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.47	2.49	Finalize
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	7.25	7.25	Finalize
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter	2.59	2.59	Finalize

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43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	4.68	4.83	Finalize
43243	Esophagogastroduodenoscopy, flexible, transoral; with injection sclerosis of esophageal/gastric varices	4.37	4.37	Finalize
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices	4.50	4.50	Finalize
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)	3.18	3.18	Finalize
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	3.66	3.66	Finalize
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)	3.18	3.21	Finalize
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	3.01	3.01	Finalize
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)	2.77	2.77	Finalize
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	3.07	3.07	Finalize
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	3.57	3.57	Finalize
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy	3.06	3.06	Finalize
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	4.68	4.83	Finalize
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	4.88	4.97	Finalize
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	3.66	3.66	Finalize

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43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease	4.11	4.25	Finalize
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	4.14	4.14	Finalize
43260	Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	5.95	5.95	Finalize
43261	Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple	6.25	6.25	Finalize
43262	Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy	6.60	6.60	Finalize
43263	Endoscopic retrograde cholangiopancreatography (ercp); with pressure measurement of sphincter of oddi	6.60	6.60	Finalize
43264	Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s)	6.73	6.73	Finalize
43265	Endoscopic retrograde cholangiopancreatography (ercp); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	8.03	8.03	Finalize
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	4.05	4.17	Finalize
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	4.21	4.26	Finalize
43273	Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (list separately in addition to code(s) for primary procedure)	2.24	2.24	Finalize
43274	Endoscopic retrograde cholangiopancreatography (ercp); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	8.48	8.58	Finalize
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	6.96	6.96	Finalize

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43276	Endoscopic retrograde cholangiopancreatography (ercp); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	8.84	8.94	Finalize
43277	Endoscopic retrograde cholangiopancreatography (ercp); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	7.00	7.00	Finalize
43278	Endoscopic retrograde cholangiopancreatography (ercp); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	7.99	8.02	Finalize
43450	Dilation of esophagus, by unguided sound or bougie, single or multiple passes	1.38	1.38	Finalize
43453	Dilation of esophagus, over guide wire	1.51	1.51	Finalize
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	4.25	4.25	Finalize
49406	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous	4.25	4.25	Finalize
49407	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal	4.50	4.50	Finalize
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	39.88	39.88	Finalize
52332	Cystourethroscopy, with insertion of indwelling ureteral stent (eg, gibbons or double-j type)	2.82	2.82	Finalize
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)	8.00	8.00	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	1.18		See II.G.3.a
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)	1.17		See II.G.3.a

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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	1.54		See II.G.3.a
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)	1.50		See II.G.3.a
63047	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; lumbar	15.37	15.37	Finalize
63048	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; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	3.47	3.47	Finalize
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)	1.53	1.53	Finalize
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	1.90	1.90	Finalize
64642	Chemodenervation of one extremity; 1-4 muscle(s)	1.65	1.65	Finalize
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)	1.22	1.22	Finalize
64644	Chemodenervation of one extremity; 5 or more muscles	1.82	1.82	Finalize
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (list separately in addition to code for primary procedure)	1.39	1.39	Finalize
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)	1.80	1.80	Finalize
64647	Chemodenervation of trunk muscle(s); 6 or more muscles	2.11	2.11	Finalize
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach	13.20	13.20	Finalize
67914	Repair of ectropion; suture	3.75	3.75	Finalize
67915	Repair of ectropion; thermocauterization	2.03	2.03	Finalize

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67916	Repair of ectropion; excision tarsal wedge	5.48	5.48	Finalize
67917	Repair of ectropion; extensive (eg, tarsal strip operations)	5.93	5.93	Finalize
67921	Repair of entropion; suture	3.47	3.47	Finalize
67922	Repair of entropion; thermocauterization	2.03	2.03	Finalize
67923	Repair of entropion; excision tarsal wedge	5.48	5.48	Finalize
67924	Repair of entropion; extensive (eg, tarsal strip or capsulopalpebral fascia repairs operation)	5.93	5.93	Finalize
69210	Removal impacted cerumen requiring instrumentation, unilateral	0.61	0.61	Finalize
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	Finalize
70460	Computed tomography, head or brain; with contrast material(s)	1.13	1.13	Finalize
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material	1.48	1.48	Finalize
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)	1.78	1.78	Finalize
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences	2.29	2.29	Finalize
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material	1.48	1.48	Finalize
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)	1.78	1.78	Finalize
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material	1.48	1.48	Finalize
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)	1.78	1.78	Finalize
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material	1.48	1.48	Finalize
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)	1.78	1.78	Finalize
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical	2.29	2.29	Finalize
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic	2.29	2.29	Finalize
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar	2.29	2.29	Finalize

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72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.81	1.81	Finalize
75896-26	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	1.31	1.31	Finalize
75896-TC	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	C	C	Finalize
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	1.65	1.65	Finalize
75898-TC	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	C	C	Finalize
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (list separately in addition to code for primary procedure)	0.38	0.38	Finalize
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)	0.54	0.54	Finalize
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.60	Finalize
77280	Therapeutic radiology simulation-aided field setting; simple	0.70	0.70	Finalize
77285	Therapeutic radiology simulation-aided field setting; intermediate	1.05	1.05	Finalize
77290	Therapeutic radiology simulation-aided field setting; complex	1.56	1.56	Finalize
77293	Respiratory motion management simulation (list separately in addition to code for primary procedure)	2.00	2.00	Finalize
77295	3-dimensional radiotherapy plan, including dose-volume histograms	4.29	4.29	Finalize
81161	Dmd (dystrophin) (eg, duchenne/becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	X	X	Finalize
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal	0.56	0.56	Finalize
88120	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual	1.20	1.20	Finalize

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88121	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology	1.00	1.00	Finalize
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	I		See II.G.3.b
88343	Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure)	I		See II.G.3.b
88365	In situ hybridization (eg, fish), per specimen; initial single probe stain procedure	1.20		See II.G.3.b
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure	1.30		See II. G.3.b
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure	1.40		See II.G3.b
88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session	I	0.91	Finalize
90785	Interactive complexity (list separately in addition to the code for primary procedure)	0.33	0.33	Finalize
90791	Psychiatric diagnostic evaluation	3.00	3.00	Finalize
90792	Psychiatric diagnostic evaluation with medical services	3.25	3.25	Finalize
90832	Psychotherapy, 30 minutes with patient and/or family member	1.50	1.50	Finalize
90833	Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	1.50	1.50	Finalize
90834	Psychotherapy, 45 minutes with patient and/or family member	2.00	2.00	Finalize
90836	Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	1.90	1.90	Finalize
90837	Psychotherapy, 60 minutes with patient and/or family member	3.00	3.00	Finalize
90838	Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	2.50	2.50	Finalize
90839	Psychotherapy for crisis; first 60 minutes	3.13	3.13	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
90840	Psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)	1.50	1.50	Finalize
90845	Psychoanalysis	2.10	2.10	Finalize
90846	Family psychotherapy (without the patient present)	2.40	2.40	Finalize
90847	Family psychotherapy (conjoint psychotherapy) (with patient present)	2.50	2.50	Finalize
90853	Group psychotherapy (other than of a multiple-family group)	0.59	0.59	Finalize
90863	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (list separately in addition to the code for primary procedure)	I	I	Finalize
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	1.75	1.75	Finalize
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	1.50	1.50	Finalize
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	3.00	3.00	Finalize
92524	Behavioral and qualitative analysis of voice and resonance	1.50	1.50	Finalize
93000	Electrocardiogram, routine ecg with at least 12 leads; with interpretation and report	0.17	0.17	Finalize
93010	Electrocardiogram, routine ecg with at least 12 leads; interpretation and report only	0.17	0.17	Finalize
93582	Percutaneous transcatheter closure of patent ductus arteriosus	12.56	12.56	Finalize
93583	Percutaneous transcatheter septal reduction therapy (eg, alcohol septal ablation) including temporary pacemaker insertion when performed	14.00	14.00	Finalize
93880	Duplex scan of extracranial arteries; complete bilateral study	0.60		See II.G.3.b
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.40		See II.G.3.b
95816	Electroencephalogram (eeg); including recording awake and drowsy	1.08	1.08	Finalize
95819	Electroencephalogram (eeg); including recording awake and asleep	1.08	1.08	Finalize
95822	Electroencephalogram (eeg); recording in coma or sleep only	1.08	1.08	Finalize
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs	1.50	1.50	Finalize
95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs	1.50	1.50	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	0.21	0.21	Finalize
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	0.18	0.18	Finalize
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	0.19	0.19	Finalize
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)	0.17	0.17	Finalize
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	0.28	0.28	Finalize
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)	0.19	0.19	Finalize
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)	0.21	0.21	Finalize
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	C	C	Finalize
98940	Chiropractic manipulative treatment (cmt); spinal, 1-2 regions	0.46	0.46	Finalize
98941	Chiropractic manipulative treatment (cmt); spinal, 3-4 regions	0.71	0.71	Finalize
98942	Chiropractic manipulative treatment (cmt); spinal, 5 regions	0.96	0.96	Finalize
99446	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review	B	B	Finalize
99447	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review	B	B	Finalize
99448	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review	B	B	Finalize

HCPCS Code	Long Descriptor	CY 2014 Interim Final Work RVU	CY 2015 Work RVU	CY 2015 Action
99449	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review	B	B	Finalize
99481	Reduce temperature of total body in a critically ill neonate, per day	C		Deleted
99482	Reduce temperature of head in a critically ill neonate, per day	C		Deleted
G0461	Immunohistochemistry or immunocytochemistry, per specimen; first single or multiplex antibody stain	0.60		Deleted
G0462	Immunohistochemistry or immunocytochemistry, per specimen; each additional single or multiplex antibody stain (list separately in addition to code for primary procedure)	0.24		Deleted

In the following section, we discuss each code for which we received a comment on the CY 2014 interim final work value or work time during the comment period for the CY 2014 final rule with comment period or for which we are modifying the CY 2014 interim final work RVU, work time or procedure status indicator for CY 2015. If a code in Table 15 is not discussed in this section, we did not receive any comments on that code and are finalizing the interim final work RVU and time without modification for CY 2015.

(1) Mohs Surgery (CPT codes 17311 and 17313)

As detailed in the CY 2014 PFS final rule with comment period, we maintained the CY 2013 work RVUs for CPT codes 17311 and 17313 codes, based upon the RUC-recommended work RVUs.

Comment: We received a comment that was supportive of the interim final work RVU.

Response: We thank the commenter for their support and are finalizing the CY 2014 interim final values for CY 2015.

(2) Breast Biopsy (CPT codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288)

For CY 2014, the CPT Editorial Panel created 14 new codes, CPT codes 19081 through 19288, to describe breast biopsy and placement of breast localization devices, and the RUC recommended work RVUs for each of these codes. In the 2014 final rule with comment period, we established interim final values for all of these codes as recommended by the RUC except for CPT code 19287 and its add-on CPT code, 19288, which are used for magnetic resonance (MR) guidance. We expressed concern that for CPT code 19287 the RUC-recommended work RVUs were too high in relation to those of other marker placement codes, and refined it to a lower value. Since we had adopted the RUC recommendation that all the add-on codes in this family have work RVUs equal to 50 percent of the base code's work RVU, our refinement of CPT code 19287 resulted in a refinement of CPT code 19288 also. We also changed the intraservice time of CPT code 19286, an add-on code, from 19 minutes to 15 minutes since we believed the intraservice time of an add-on code should not be higher than its base code and the base code for CPT code 19286, has an intraservice time of 15 minutes.

Comment: Several commenters disagreed with the new CPT coding structure for breast biopsy and placement of breast localization devices because, unlike the predecessor structure, it fails to distinguish between the two types of biopsy devices - standard core needle and vacuum assisted. One commenter suggested that the payment should be higher when services are vacuum assisted, and suggested that CMS create a modifier to report when these services are furnished using a vacuum assisted biopsy or create a series of G-codes that distinguish between standard core needle biopsy and vacuum assisted biopsy.

Response: We prefer to use the CPT coding structure unless a programmatic need suggests that an alternative coding structure is preferable. In this case, we believe that we can

pay appropriately for these services using the new CPT coding structure. To the extent that the commenters think the CPT coding system is not ideal for these services, we believe the CPT Editorial Panel is the appropriate forum for this concern. The commenters are mistaken regarding how the inputs for these codes were determined as they are based upon the typical service being vacuum assisted.

Comment: Several commenters disagreed with the interim final work RVUs we established for CPT codes 19287 and 19288, stating that the higher RUC-recommended RVUs were more appropriate and would maintain relativity within the family. The commenters stated that these services have longer intraservice time than other codes in the marker placement family, are of high intensity, produce high patient and family anxiety, and have higher malpractice costs. One commenter requested that the entire breast biopsy code family be referred to refinement. Other commenters requested refinement panel review of selected codes within this family.

Response: Based upon this request, we referred this family of codes to the CY 2014 multi-specialty refinement panel for further review. Prior to CY 2014, breast biopsies and marker placements were billed using a single code. In addition, the appropriate image guidance code was separately billed. Prior to CY 2014, there were individual guidance codes for the different types of guidance including MR and stereotactic guidance.

For CY 2013, the MR guidance code, CPT code 77032, had a lower work RVU than the stereotactic guidance code, CPT code 77031. Combining the values for the marker placement or biopsy codes with the guidance codes should not, in our view, result in a change in the rank order of the guidance. Accordingly, we do not believe the bundled code that includes MR guidance should now be valued significantly higher than one that includes the stereotactic guidance. Also, the refinement panel discussions did not provide new clinical information. Therefore, we

continue to believe the CY 2014 interim final values are appropriate for CPT codes 19287 and 19288, and are finalizing them for CY 2015.

Comment: Commenters stated that the RUC-recommended intraservice time of 19 minutes for CPT code 19286, which is an add-on code, was incorrect and that the code should have the same intraservice time as its base code (15 minutes) rather than the 14 minutes assigned by CMS. The commenter said that this was consistent with the other base code/add-on relationships across the family.

Response: We agree and are finalizing the intraservice time for CPT code 19286 at 15 minutes.

Comment: In response to our request for confirmation that a post procedure mammogram is typically furnished with a breast marker placement procedure, commenters agreed that it was. However, they disagreed with our assertion that if it was typical it should be bundled with the appropriate breast marker procedures. Commenters said that it should be a separately reportable service because it requires additional work not captured by the codes in this family.

Response: We thank commenters for their feedback. We are not bundling post procedure mammograms with the appropriate breast marker codes at this time, but will consider whether as a services that typically occur together they should be bundled.

(3) Hip and Knee Replacement (CPT Codes 27130, 27446 and 27447)

In the CY 2014 final rule with comment period we established interim final values for three CPT codes for hip and knee replacements that had previously been identified as potentially misvalued codes under the CMS high expenditure procedural code screen. For CY 2014, we established the RUC-recommended work value of 17.48 as interim final work RVUs for CPT code 27446. As we explained in the CY 2014 final rule with comment period, we established

interim final work RVUs for CPT codes 27130 and 27447 that varied from those recommended by the RUC based upon information that we received from the relevant specialty societies. We noted that the information presented by the specialty societies and the RUC raised concerns regarding the appropriate valuation of these services, especially related to the use of the best data source for determining the intraservice time involved in furnishing PFS services. Specifically, there was significant variation between the time values estimated through a survey versus those collected through specialty databases. We characterized our concerns saying, "The divergent recommendations from the specialty societies and the RUC regarding the accuracy of the estimates of time for these services, including both the source of time estimates for the procedure itself as well as the inpatient and outpatient visits included in the global periods for these codes, lead us to take a cautious approach in valuing these services."

With regard to the specific valuations, we agreed with the RUC's recommendation to value CPT codes 27130 and 27447 equally. We explained that we modified the RUC-recommended work RVUs for these two codes to reflect the visits in the global period as recommended by the specialty societies, resulting in a 1.12 work RVU increase from the RUC-recommended value for each code. Accordingly, we assigned CPT codes 27130 and 27447 an interim final work RVU of 20.72. We sought public comment regarding, not only the appropriate work RVUs for these services, but also the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We also sought public comment on the use of specialty databases as compared to surveys for determining time values, potential sources of objective data regarding procedure times, and levels of visits furnished during the global periods for the services described by these codes.

Comment: The RUC submitted comments explaining how it reached its recommendations for these codes and that it followed its process consistently in developing its recommendations on these codes. All those who commented specifically on the interim final work RVUs for these codes objected to the interim final work RVUs - some citing potential access problems. Commenters suggested that we use more reliable time data. Commenters suggested that valuation should be based on actual time data, which demonstrates that the time for this code has not changed since the last valuation; and thus the work RVUs should not decrease from the CY 2013 values. Among the commenters' suggestions were using data from the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR), which includes data on more than 15,000 total lower extremity joint arthroplasty procedures, including time in/time out data for at least half of the procedures, and working with the specialty societies to explore the best data collection methods. A commenter suggested restoring the CY 2013 work RVUs until additional time data are available. Another commenter suggested valuing these services utilizing a reverse building block methodology resulting in work RVU of 21.18 for CPT codes 27130 and 22.11 for CPT code 27447. A commenter stated that the hip and knee replacement codes should be valued differently since they are clinically different procedures. Two commenters expressed concern regarding the use of a final rule to establish interim values for established hip and knee procedures due to the lack of opportunity it provides stakeholders to analyze and comment on reductions prior to implementation.

Response: In the CY 2014 final rule with comment period, we noted concerns about the time data used in valuing these services and requested additional input from stakeholders regarding using other sources of data beyond the surveys typically used by the RUC. We do not believe that we received the kind of information and the level of detail about the other types of data suggested by commenters that we would need to be able to use routinely in valuing

procedures. We will continue to explore the use of other data on time. As we discuss in section II.B. we have engaged contractors to assist us in exploring alternative data sources to use in determining the times associated with particular services. At this time, we are not convinced that data from another source would result in an improved value for these services. Nor did we find the reasons given for modifying the interim final work values established in CY 2014. The interim final values are based upon the best data we have available and preserve appropriate relativity with other codes. Accordingly, we are finalizing the interim final values for these procedures.

(4) Transcatheter Placement Intravascular Stent (CPT Code 37236, 37237, 37238, and 37239)

For CY 2014, we established the RUC-recommended work RVUs for newly created CPT codes 37236, 37237, and 37238 as the interim final values. We disagreed with the RUC-recommended work RVU for CPT code 37239, which is the add-on code to CPT code 37238, for the placement of an intravascular stent in each additional vein. As we described in the CY 2014 final rule with comment period we believe that the work for placement of an additional stent in a vein should bear the same relationship to the work of placing an initial stent in the vein as the placement of an additional stent in an artery to the placement of the initial stent in an artery.

Comment: Many commenters indicated that our valuation of CPT code 37239 was inappropriate. They indicated that instead we should use the RUC's recommended work RVU of 3.34 for this code since the procedure is more intense and requires more physician work than would result from the comparison made by CMS. One commenter requested that CPT code 37239 be referred to the refinement panel.

Response: After re-review, we continue to believe that the ratio of the work of the placement of the initial stent to the placement of additional stents is the same whether the stents

are placed in an artery or a vein, and accordingly the appropriate ratio is found in the RUC-recommended work RVUs of CPT codes 37236 and 37237, the comparable codes for the arteries. For that reason, we are finalizing our CY 2014 interim final values. Additionally, we did not refer these codes for refinement panel review because the criteria for refinement panel review were not met.

(5) Embolization and Occlusion Procedures (CPT codes 37242 and 37243)

For CY 2014, we established interim final work RVUs for these two codes based upon the survey's 25th percentile. As we discussed in the CY 2014 interim final rule with comment period, we believed that the RUC-recommended work RVU for CPT code 37242 did not adequately take into account the substantial decrease in intraservice time. We indicated that we believed that the survey's 25th percentile work RVU of 10.05 was more consistent with the decreases in intraservice time since its last valuation and more appropriately reflected the work of the procedure. Similarly, we did not believe that the RUC-recommended work RVU for CPT code 37243 adequately considered the substantial decrease in intraservice time for the procedure; and we also use the survey's 25th percentile for CPT code 37243.

Comment: Many commenters disagreed with our interim final valuation of 37242, including one who recommended a work RVU of 11.98. One commenter also believed the work RVU assigned to CPT code 37243 was inappropriate and recommended instead a work RVU of 14.00. Commenters requested that the family of codes be referred for refinement.

Response: After consideration of the comments, we continue to believe that work RVUs should reflect the decreases in intraservice time that have occurred since the last valuation. As a result, we continue to believe that our CY 2014 interim final values are most appropriate and are finalizing them for CY 2015. Additionally, we did not refer these codes for refinement panel review because the criteria for refinement panel review were not met.

(6) Rigid Transoral Esophagoscopy (CPT Codes 43191, 43192, 43193, 43194, 43195 and 43196)

We established CY 2014 interim final work RVUs for the rigid transoral esophagoscopy codes using a ratio of 1 RVU per 10 minutes of intraservice time, resulting in a RVU of 2.00 for CPT code 43191, 3.00 for CPT code 43193, 3.00 for CPT code 43194, 3.00 for CPT code 43195, and 3.30 for CPT code 43196. As we detailed in the CY 2014 final rule with comment period, the surveys showed that this ratio was reflected for about half of the rigid transoral esophagoscopy codes. Additionally, we noted that this ratio was further supported by the relationship between the CY 2013 work value of 1.59 RVUs for CPT code 43200 (Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)) and its intraservice time of 15 minutes. For CPT code 43192, the 1 work RVU per 10 minutes ratio resulted in a value that was less than the survey low, and thus did not appear to be appropriate for this procedure. Therefore, we established a CY 2014 interim final work RVU for CPT code 43192 of 2.45 based upon the survey low.

Comment: Multiple commenters objected to the interim final work RVUs assigned to CPT codes 43191-43196, and expressed dissatisfaction with CMS's explanation for the valuations. The commenters specifically noted that CMS did not account for the difference in intensity between flexible and rigid scopes now that there are separate codes for these procedures. The commenters also suggested that the reduction in time in the RUC recommendations for codes 43191, 43193, 43195, and 43196 was also based on data from procedures with flexible scopes. The commenters also stated that our valuation of services based upon 1 work RVU per 10 minutes of intraservice time was inappropriate and was based on the survey low, which is an anomalous outlier. The commenters suggested the following work RVUs based upon the RUC recommended values: 2.78 for CPT code 43191, 3.21 for CPT code

43192, 3.36 for CPT code 43193, 3.99 for CPT code 43194, 3.21 for CPT code 43195 and 3.36 or CPT code 43196. Finally, the commenters asked that all these codes be referred to a refinement panel for reconsideration.

Response: After consideration of the comments, we agree that modification of the CY 2014 interim final values is appropriate. Based upon the information provided in comments and further investigation, we believe that greater intensity is involved in furnishing rigid than flexible transoral esophagoscopy. Accordingly, rather than assigning 1 work RVU per 10 minutes of intraservice time as we did for the CY 2014 interim final, we are assigning a final work RVU to the base code, CPT code 41391, of 2.49. This work RVU is based on increasing the work RVU of the previous comparable code (1.59) to reflect the percentage increase in time for the CY 2014 code. For the remaining rigid esophagoscopy codes, we developed RVUs by starting with the RVUs for the corresponding flexible esophagoscopy codes, and increasing those values by adding the difference between the base flexible esophagoscopy and the base rigid esophagoscopy codes to arrive at final RVUs. We are establishing a final work RVU of 2.79 to CPT code 43192, 2.79 to CPT code 43193, 3.51 to CPT code 43194, 3.07 to CPT code 43195, and 3.31 to CPT code 43196. These codes were not referred to refinement because the request did not meet the criteria for referral.

(7) Flexible Transnasal Esophagoscopy (CPT codes 43197 and 43198)

We established CY 2014 interim final work RVUs of 1.48 for CPT code 43197 and 1.78 for CPT code 43198. As detailed in the CY 2014 final rule with comment period, we removed 2 minutes of the pre-scrub, dress and wait preservice time from the calculation of the work RVUs that we established for CY 2014 for CPT codes 43200 and 43202 because we believed that unlike the transoral codes, which they correspond to, the transnasal services are not typically furnished with moderate sedation.

Comment: Multiple commenters objected to the work RVUs for these codes and in particular to CMS basing its valuation on the fact that these codes typically do not involve moderate sedation. Although the commenters agreed that these codes typically do not involve moderate sedation, they said that procedures involving local/topical anesthesia often take more work than those involving general sedation due to the difficulties of furnishing services to a conscious and often anxious patient. Some also noted that it ignores the time necessary to apply local/topical anesthesia and wait for it to take effect. A commenter urged CMS to establish values based upon the RUC recommendations. Commenters requested that these codes be referred for refinement.

Response: After consideration of the comments, we agree that the work RVUs for these codes should not be reduced because moderate sedation is not typically used. Accordingly, we agree with the RUC recommendation to assign the same work RVUs to these codes as to CPT code 43200 (Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed) and 43202 (Esophagoscopy, flexible, transoral; with biopsy, single or multiple) the comparable transoral codes. We are finalizing work RVUs of 1.52 and 1.82 for CPT codes 43197 and 43198, respectively. We did not refer these codes to refinement because the request did not meet the criteria for refinement panel review.

(8) Flexible Transoral Esophagoscopy, (CPT Codes 43200, 43202, 43204, 43205, 43211, 43212, 43213, 43214, 43215, 43227, 43229, 43231, and 43232)

We established CY 2014 interim final work RVUs for the flexible transoral esophagoscopy family, which are detailed in Table 15. As we described in the CY 2014 final rule with comment period, to establish work values for these codes we used a variety of methodologies as did the RUC. The methodologies used by CMS And the RUC include basing values on the surveys (either medians or 25th percentiles), crosswalking values to other codes,

using the building block methodology, and valuing a family of codes based on the incremental differences in the work RVUs between the codes being valued and another family of codes. As we did for the rigid transoral esophagoscopy codes, in addition to the methodologies used by the RUC, we also reduced the work RVUs for particular codes in direct proportion to the reduction in times that were recommended by the RUC. Using these methodologies, we assigned the RUC-recommended work RVUs for five codes in this family; for the other eight codes we used these same methodologies but because of different values for a base code or variation in the crosswalk selected we obtained different values.

Comment: Commenters objected to the interim final RVUs we assigned for CPT code 43200, the base code for flexible transoral esophagoscopy, because they did not believe the work RVU for the code should be less than they were as of CY 2013 when there was a single code to report both flexible and rigid esophagoscopy services. Commenters also disagreed with the way we used standard methodologies to value many of these codes, including using the ratio of 1 work RVU per 10 minutes of intraservice time to CPT code 43200. Commenters requested that we accept the RUC values for all the flexible transoral esophagoscopy codes and asked that we refer all these codes to the refinement panel.

Response: Although refinement was requested for all of the flexible transoral esophagoscopy codes, we found that the codes (CPT codes 43204, 43205 and 43233) met the refinement criteria, and those were referred to the refinement panel. After consideration of the comments and the refinement panel results, we are revising the work RVUs for many of the codes in this family.

For CPT code 43200, which is the base code for flexible transoral esophagoscopy, we agree with commenters that another methodology is preferable to applying the work RVU ratio of 1 RVU per 10 minutes of intraservice time. In revaluing this service, we subtracted 0.07 to

account for the 3 minute decrease in postservice time since the last valuation from the CY 2013 work RVU for the predecessor base code, which resulted in a work RVU of 1.52. We are finalizing this work RVU.

The CY 2014 interim final work RVUs for CPT codes 43201, 43202, 43204, 43205 and 43215 were all based upon methodologies using the work RVU of the base code, 43200. As we are establishing a final value for CPT code 43200 that is higher than the CY 2014 interim final value, we are also adjusting the work RVUs for the other codes based upon the new work RVU for CPT code 43200. We are finalizing a work RVU of 1.82 for 43201, 1.82 for 43202, 2.43 for 43204, 2.54 for 43205, and 2.54 for 43215.

CPT codes 43204 and 43205 were considered by the refinement panel. The refinement panel median for each of these codes was 2.77 and 2.88, respectively. The refinement panel discussion reiterated the information presented to the RUC and in the comments in response to the CY 2014 final rule with comment period, such as that the typical patient for these codes are sicker and thus the work is more intense. Because we do not agree with commenters' contention that higher work RVUs are warranted since these codes involve the sicker patients or that our methodology for calculating the interim final RVUs was inappropriate, we are establishing final values determined using these methodologies. However, due to the change in the base code, CPT code 43200, as discussed in the previous paragraph the final values for these codes are higher than the interim final values.

In the CY 2014 final rule with comment period, we assigned an interim final work RVU of 4.21 to CPT code 43211 by using a comparable esophagogastroduodenoscopy (EGD) code and subtracting the difference in work between the base esophagoscopy and base EGD codes. After consideration of the comments that indicated the interim final work RVU of 4.21 was too low, we believe this code should instead be crosswalked to CPT code 31636 (Bronchoscopy

bronch stents), which we believe is a comparable service with comparable intensity. It has the same intraservice time and slightly higher total time. As a result we are finalizing a work RVU of 4.30.

As we noted in the CY 2014 final rule with comment period, we crosswalked the interim final work RVU for CPT 43212 to that of CPT code 43214. Since we are increasing the work RVU for CPT code 43214, we are also increasing the work RVU for CPT code 43212, which is consistent with comments that we had undervalued this procedure.

As we detailed in the CY 2014 final rule with comment period, we based the work RVU of 4.73 for CPT code 43213 on the value of CPT code 43220, increased proportionately to reflect the longer intraservice time of CPT code 43213. The refinement panel median was 5.00 for this code. No new information was presented at the refinement panel. We continue to believe that 4.73 is the appropriate work RVU and are finalizing it.

Based upon the information presented by commenters about the typical patient and the advanced skills required for the procedure, we are changing our method of valuing CPT code 43214. We believe it should be crosswalked to CPT 52214 (cystoscopy), which we believe is similar in intensity. This results in a final work RVU of 3.50 as compared to an interim final of 3.38. This refinement also supports the belief made by commenters that the work of CPT code 43214 is greater than the interim final work RVU. Therefore, we are finalizing a work RVU of 3.50 for CPT code 43214.

For CPT code 43227, we modified the CY 2013 work RVU to reflect the percentage decrease in intraservice time of 36 minutes to 30 minutes in the RUC recommendation to establish a CY 2014 interim final value of 2.99. The commenters stated that the survey validates the RUC recommendation of 3.26 and that the drop in intraservice time that upon which we based our change in the work RVU was inappropriate since the intraservice time had not really

changed. They contend that the change was from moving the time for moderate sedation from intraservice to preservice. We disagree. We have no information from the RUC that leads us to believe that when the pre-service packages were developed several years ago and moderate sedation was explicitly recognized as a pre-service item that the RUC also intended CMS to assume that the intraservice times were no longer correct. We believe that our proposed valuation methodology is correct and thus are finalizing a work RUV of 2.99.

Commenters, disagreeing with our crosswalk of CPT code 43229 to CPT code 43232, stated that the two codes were not comparable. We disagree. We continue to believe this crosswalk is appropriate as the times and intensities are quite similar. We note that the RUC also bases crosswalks on the comparability of time and intensity of codes and not on the clinical similarity of work. Thus, we will continue this crosswalk. However, as discussed below, we are refining the interim final value of CPT code 43232 to 3.59 and thus are finalizing the work RVU of 3.59 for CPT code 43229.

For CPT code 43231, we added the work of an endobronchial ultrasound (EBUS) to the work of the base esophagoscopy code to arrive at our interim final value. The commenters disagreed with our approach, stating that the EBUS code is an add-on code and as such does not have pre- and postservice work. We agree that pre- and postservice work is not included in the EBUS code nor should it be for the ultrasound portion of the examination of esophagus. Therefore, we are finalizing a work RVU of 2.90.

For CPT code 43232, the commenters stated our interim final value is too low and that the work involved in this code is appropriately reflected in the RUC recommendation. They objected to our basing the work RVU for 43232 on the difference between the RUC-recommended values for this code and CPT code 43231. We learned from the comments that the typical patient for this service has advanced cancer and agree that our interim final value may not

represent the full extent of the work involved in this procedure. Therefore, we are crosswalking this code to CPT code 36595 (Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access), which has identical intraservice time, slightly less total time, and a slightly higher intensity and are finalizing a work RVU of 3.59.

(10) Esophagogastroduodenoscopy (EGD) (CPT codes 43233, 43235, 43236, 43237, 43238, 43239, 43242, 43244, 43246, 43247, 43249, 43253, 43254, 43255, 43257, 43259, 43266, and 43270.

We established interim final work RVUs for various EGD codes in the CY 2014 final rule with comment period. In this section, we discuss the 18 EGD codes on which we received comments disagreeing with or making recommendations for changes in our interim final values. As we detailed in the CY 2014 final rule with comment period, we valued many of these codes by adding the additional work of an EGD to the comparable esophagoscopy (ESO) code. We determined the additional work of an EGD by subtracting the work RVU of CPT code 43200, the base ESO code, from the work of CPT code 43235, the base EGD code. For example, CPT code 43233 is an identical procedure to CPT code 43214 except that it uses EGD rather than ESO. We valued it by adding the additional work of EGD to the work RVU of CPT code 43214, resulting in an interim final work RVU of 4.05. We valued the additional work the same way the RUC did in its recommendations. The following EGD codes were valued in the same way using the code in parentheses as the corresponding ESO code: 43233 (43214), 43236 (43201), 43237 (43231), 43238 (43232), 43247 (43215), 43254 (43211), 43255 (43227), 43266 (43212), and 43270 (43229). In valuing CPT codes 43235, we agreed with the RUC recommended work RVU difference between this EGD base code and the esophagoscopy base code, CPT 43200 but applied the difference to our CY 2014 RVU values. In a similar fashion, in valuing CPT code

43242 we agreed with the RUC recommended methodology of which took the increment between CPT code 43238 and CPT code 43237 but we applied the difference to our CY 2014 values. In order to value other EGD codes, we crosswalked the services to similar procedures; specifically for CY 2014 we crosswalked CPT codes 43239 to 43236, 43246 to 43255, 43253 to 43242 and 43257 to 43238. We valued CPT codes 43244 and 43249 through acceptance of the RUC work RVU recommendation. Lastly, we valued CPT code 43259 by adjusting the CY 2013 work RVU to account for the CY 2014 RUC recommended reduction in total time.

Comment: For all codes, commenters objected to our work RVUs and said that our reductions from the RUC recommendations were based on a decrease in intraservice time that did not reflect a change in the time required to furnish the procedures but rather only a change in which part of the procedure the RUC includes the moderate sedation time. Commenters disagree with our valuing CPT code 43233 based on the value of CPT code 43214, saying that CPT code 43233 is more intense due to the risk of perforation, and that the achalasia patients are at high risk and poor candidates for surgery. Commenters disagreed with our methodology for valuing CPT code 43235, and suggested that we use the RUC crosswalk to CPT code 31579, contending that the slight reductions in pre- and post-service times are consistent with the slight drop in the RUC-recommended RVU. For CPT code 43237, commenters also noted a rank order anomaly because the interim final work RVU for this code is the same as for CPT code 43251. Commenters said that the robust survey data on CPT code 43238 should override CMS decisions. With regard to CPT code 43239, commenters suggest that the survey is wrong and further point to the fact that our valuation results in the same value for CPT code 43239 as the base EGD code, which they state is not appropriate due to the additional work in CPT code 43239. Commenters disagreed with our value for CPT code 43242 stating that we inappropriately valued CPT code 43259, which we used in calculating the work RVUs for CPT

code 43242. Commenters objected to our value of CPT code 43246 because they disagree with the work RVU for the code that it is crosswalked to, CPT code 43255. Commenters urged us to modify our work RVU for CPT code 43247 to equal the RUC recommendation. For CPT code 43253, commenters did not disagree with the valuation approach, but disagreed with the valuation we had assigned to the base code, CPT code 43259, which affected the valuation of CPT code 43253. Comments indicated that they did not understand how the value of CPT code 43254 was derived. Commenters indicated that they disagreed with the reduction in the work in CPT code 43255 due to a decrease in time. They also cited that this was an emergency procedure in unstable patients and that it was more difficult to control bleeding in the stomach than in the esophagus. For CPT code 43257, commenters disagreed with our crosswalk to CPT code 43238 indicating that CPT code 43257 was more intense than CPT code 43238. Commenters acknowledged that reduced times should result in reduced work, but disagreed with our proportional reduction approach. Commenters agreed with our approach to valuing CPT code 43266, but disagreed with the valuation of the CPT code 43212, that we used as the base. With regard to CPT code 43270, commenters disagreed with using CPT code 43229 as the base.

Response: For each of these codes, commenters were concerned that we did not accept the RUC-recommended values. Their common reasoning for urging us to accept the RUC-recommended values was that moderate sedation time had been removed from intraservice time and that these intraservice time changes should not result in a change in the RUC-recommended RVU. However, for CPT codes 43233, 43236, 43237, 43238, 43247, 43254, 43255, 43266, and 43270, we used the standard methodology described above for valuing EGD codes and did not base our values on the time change. Thus, any refinements to the RUC recommendations for the EGD codes are solely due to refinements in the ESO codes. We discussed our valuations of these codes in the previous section. Since we have finalized most of the ESO codes at higher levels

than the CY 2014 interim final values, we are making corresponding increases in the EGD codes. Therefore, we are finalizing these codes at the following work RVUs: 43233 at 4.17, 43235 at 2.19, 43236 at 2.49, 43237 at 3.57, 43238 at 4.26, 43247 at 3.21, 43254 at 4.97, 43255 at 3.66, 43266 at 4.17, and 43270 at 4.26.

CPT code 43233 was referred to the refinement panel and received a median work RVU of 4.26. As outlined above, we are finalizing a work RVU of 4.17 for CPT code 43233 at 4.17, which is higher than our interim value of 4.05, but consistent with our valuation of the other EGD codes. We do not believe that the comments provided at the refinement panel justify adoption of the higher median value.

The interim final work value of CPT code 43239 was crosswalked to the work RVU of CPT code 43236. Since we increased the final work RVU from the interim final for this code, the final work RUV of CPT code 43239 increases to 2.49.

(11) Endoscopic Retrograde Cholangiopancreatography (ERCP) (CPT codes 43263, 43274, 43276, 43277 and 43278)

In the CY 2014 final rule with comment period we established interim final work RVUs for several ERCP codes due to coding revisions. For all those codes not discussed in this section, we are finalizing the interim final work RVUs. For CPT code 43263, we established an interim final work RVU based upon a crosswalk to CPT code 43262. As we detailed in the CY 2014 final rule with comment period, we valued CPT codes 43274, 43276, and 43278 using the same formula that the RUC used in determining its recommendations, but substituting our interim final work RVUs for codes used in the formula for the RUC-recommended values. CPT code 43277 was valued using the survey 25th percentile.

Comment: Commenters objected to our valuation of CPT 43263 based upon a crosswalk to CPT code 43262, saying that CPT 43263 is more intense and has greater risks than CPT code

43262. Commenters also indicated that we underestimated the intensity of CPT code 43276 indicating that CPT code 43276 typically involves replacing stents that are overgrown with cancerous tissues. They also said that we underestimated the intensity of CPT coded 43274 and 43277. Commenters further took issue with our valuing CPT code 43277 based upon the survey when most codes in this family were valued based upon the incremental formula. Commenters stated that CPT code 43278 is valued incorrectly because we did not correctly value CPT code 43229, which is used in the formula we used to value CPT code 43278.

Response: After consideration of the comments, we continue to believe that CPT code 43263 is the appropriate crosswalk for CPT code 43262 and we are finalizing a work RVU of 6.60 for that code. With regard to CPT code 43274, we continue to believe the formula described in the CY 2014 final rule with comment period is the appropriate methodology. We are finalizing a work RVU of 8.58 for CPT code 43274 using the final values for the codes used in the formula and thus increasing the work RVU from the interim final value of 8.48. Similarly, we are finalizing a work RVU of 8.94 for CPT code 43276 based upon the formula described in the CY 2014 final rule with comment period adjusted for changes in the final work RVUs for values used in the formula. For CPT code 43277, we continue to believe the survey 25th percentile is appropriate. This valuation is supported by a drop in the intraservice time from the code it replaces. Thus, we are finalizing the interim final work RVU of 7.00. For CPT code 43278, we continue to believe use of the RUC formula for this code is most appropriate, and we are adjusting the work RVU to reflect final work RVUs for values used in the formula. The final work RVU for CPT code 43278 is 8.

(12) Spinal Injections (CPT codes 62310, 62311, 62318 and 62319)

We proposed new work RVUs for these codes in the PFS proposed rule. (79 FR 40338-40339). See section II.B.3 for a discussion of the valuation of these codes, and a summary of public comments and our responses.

(13) Laminectomy (CPT Codes 63045, 63046, 63047 and 63048)

We established interim final work RVUs for CPT codes 63047 and 63048 for CY 2014. As we indicated in the CY 2014 final rule with comment period, we had identified CPT code 63047 as potentially misvalued through the high expenditure procedure code screen and the RUC included a recommendation for CPT code 63048. We noted that, to appropriately value these codes, we need to consider the other two codes in this family: CPT codes 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) and 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). Although we did not receive recommendations for CPT codes 63045 and 63046, we established CY 2014 interim final work RVUs for CPT codes 63047 and 63048 of 15.37 and 3.47, respectively, based upon the RUC recommendations. We noted that we expected to review these values in concert with the RUC recommendations for CPT codes 63045 and 63046 when we received them.

Comment: Commenters questioned our determination that CPT codes 63047, 63048, 63045 and 63046 constituted a family, noting that CPT codes 63045 and 63046 require different work. Commenters questioned the value of resurveying this set of codes as a family since CPT codes 63045 and 63046 constitute a small percentage of the total volume of these codes. The survey of CPT codes 63047 and 63048 did not reveal significant change in the values of the

codes, and the work involved in resurveying would be burdensome for those involved. One commenter urged us to withdraw our request to survey these codes.

Response: We continue to believe that it is appropriate to value a family of codes together in order to maintain relativity. We also continue to believe that CPT codes 63045 and 63046 are indeed in the same family as CPT codes 63047 and 63048 due to similarity of service. We have received new RUC recommendations for CPT code 63045 and 63046, but did not receive them in time to include in this rule. As a result, we will finalize the interim work values for CPT codes 63047 and 63048 for CY 2015.

(14) Chemodenervation of Muscles (CPT codes 64616, 64617, 64642, 64643, 64644, and 64645)

We assigned refined interim final work RVU values of 1.53 to CPT code 64616 and 1.90 to CPT code 64617. As detailed in the CY 2014 final rule with comment period, we refined the RUC-recommended work RVUs of 1.79 for CPT code 64616 and 2.06 for CPT code 64617 to reflect the deletion of an outpatient visit that was included in the predecessor code, CPT code 64613 (chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)). We also explained that since CPT code 64617, chemodenervation of the larynx, includes EMG guidance when furnished we determined the interim final work RVU by adding the work RVU for CPT code 95874 (Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)) to the CY 2013 work RVU for CPT 64616.

For CY 2014, we assigned interim final work RVUs for CPT code 64643 and CPT code 64645 of 1.22 and 1.39, respectively. As we explained in the CY 2014 final rule with comment period, we refined the RUC-recommended work RVUs for these add-on codes by subtracting the RVUs to account for 19 minutes of pre-service time and the decrease in time for furnishing the

add-on service. Additionally, we based the global period for these codes on the predecessor code, CPT code 64614 (chemodenervation of muscle(s); extremity and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)), which was deleted for CY 2014. Therefore, we assigned 10-day global periods to the services.

Comment: Most commenters disagreed with the CY 2014 interim final work RVU valuations for CPT codes 64616, 64643, and 64645. One commenter stated that the work RVU for the predecessor code, CPT code 64614, did not take into account the full level of intensity, time, and work that it takes to perform the service. This commenter also disagreed with the times for this service. Several commenters disagreed with the valuation of CPT code 64616 saying that we ignored the RUC recommendation which was based on survey data and RUC deliberations and asked that we value the code based upon the RUC recommendation. Several commenters disagreed with the valuations for CPT codes 64643 and 64645 saying that CMS did not explain our valuation, ignored the fact that the RUC discounted the add-on codes based on the pre- and post-service time and did not articulate any basis for our valuation decision. Several commenters requested refinement of the codes in the chemodenervation family.

Response: After consideration of the comments we are finalizing the interim final work RVUs and time for these codes. We continue to believe that our valuations for this family take into account the full level of intensity, time, and work that are required to furnish these services. Additionally, we disagree with commenters that we did not explain our valuation of CPT codes 64643 and 64645. In the CY 2014 final rule with comment period, we detail and thoroughly explain the methodology utilized to value CPT codes 64643 and 64645. Additionally, the request for refinement panel review was not granted as the criteria for refinement were not met.

(15) Impacted Cerumen (CPT code 69210)

After it was identified as a potentially misvalued code pursuant to the CMS high expenditure screen, CPT code 69210, which describes removal of impacted cerumen, was revised from being applicable to ''1 or both ears'' to a unilateral code effective January 1, 2014. For Medicare purposes we limited the code to billing once whether it was furnished unilaterally or bilaterally because we believed the procedure would typically be furnished in both ears as the physiologic processes that create cerumen impaction likely would affect both ears. Similarly, we continued the CY 2013 value as our interim final CY 2014 value since for Medicare purposes the service was unchanged.

Comment: Commenters requested that we allow CPT code 69210 to be billed twice when it is furnished bilaterally, consistent with code descriptor. Commenters stated that our assumption regarding the physiologic processes that create cerumen was flawed and requested we provide a clinical rationale and/or literature to support our claim. Lastly, the commenters requested guidance from the agency as to how best deal with this CPT code; specifically, if it should be sent to CPT for clarification or if not, that we provide further guidance as to how this procedure should be billed using the new code.

Response: We continue to believe that the procedure will be furnished in both ears as the physiologic processes that create cerumen impaction likely would affect both ears. As a result, we will continue to allow only one unit of CPT 69210 to be billed when furnished bilaterally and are finalizing our CY 2014 interim final work RVU for this service.

(16) Magnetic Resonance Imaging (MRI) Brain (CPT codes 77001, 77002, and 77003)

As detailed in the CY 2014 final rule with comment period, we agreed with the RUC-recommended values for CPT codes 77001, 77002 and 77003 but were concerned that the recommended intraservice times for all three codes was generally higher than the procedure codes with which they were typically billed. We sought additional public comment and input

from the RUC and other stakeholders regarding the appropriate relationship between the intraservice time associated with fluoroscopic guidance and the intraservice time of the procedure codes with which they are typically billed.

Comment: Some commenters disagreed with the concern expressed by CMS that the intraservice time for codes 77001, 77002 and 77003 is higher than the codes alongside which they are typically billed, as the commenters believed that the combinations being used to support this concern were not appropriate, and they requested additional examples to support its concern. The commenters believed that the concerns CMS expressed are unfounded and that we should assign work RVUs of 0.38, 0.54, and 0.60 for CPT code 77001, 77002, and 77003, respectively.

Response: We continue to have concerns regarding the appropriate relationship between the intraservice time associated with fluoroscopic guidance and the intraservice time of the procedure codes with which they are typically billed and will continue to study this issue. We are finalizing the CY 2014 interim final values for CY 2015.

(17) Immunohistochemistry (CPT codes 88342 and 88343 and HCPCS codes G0461 and G0462)

These codes were revised for CY 2015. For discussion of valuation for CY 2015, see section II.G.3.b.

(18) Optical Endomicroscopy (Code 88375)

As detailed in the CY 2014 final rule with comment period, we believed that the typical optical endomicroscopy case would involve only the endoscopist, and CPT codes 43206 and 43253 were valued to reflect this. Accordingly, we believed a separate payment for CPT code 88375 would result in double payment for a portion of the overall optical endomicroscopy service. Therefore, we assigned a PFS procedure status of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) to CPT code 88375.

Comment: Multiple commenters objected to CMS's decision to assign a PFS status indicator of "I" to code 88375, stating that the code already includes distinctions that would prevent a physician from billing the code when it would double count work. The commenters urge CMS to assign CPT code 88375 a Medicare status of A (Active Code), and to immediately publish RVUs associated with the service.

Response: In our re-review of this procedure and consideration of the information provided by commenters, we believe the coding is adequate to avoid double payment for a portion of the service. Accordingly, we assigned a Medicare status indicator of A (Active). To value this service, we based the RVUs on those assigned to CPT code 88329, adjusted for the difference in intraservice time between the two codes. We are assigning a final work RVU of 0.91 for CPT code 88375 for CY 2015.

(19) Speech Language (CPT codes 92521, 92522, 92523 and 92524)

In CY 2014, we assigned CY 2014 interim final work RVUs of 1.75 and 1.50 for CPT codes 92521 and 92522, respectively, as the HCPAC recommended. For CPT code 92523, we disagreed with the HCPAC-recommended work RVU of 3.36. We believed that the appropriate value for 60 minutes of work for the speech evaluation codes was reflected in CPT code 92522, for which the HCPAC recommended 1.50 RVUs. Because the intraservice time for CPT code 92523 was twice that for CPT code 92522, we assigned a work RVU of 3.0 to CPT code 92523. Similarly, since CPT codes 92524 and 92522 had identical intraservice time recommendations and similar descriptions of work we believed that the work RVU for CPT code 92524 should be the same as the work RVU for CPT code 95922. Therefore, we assigned a work RVU of 1.50 to CPT code 92524.

Comment: Commenters disagreed with the interim final work RVUs assigned to CPT codes 92523 and 92524, saying they based on inaccurate assumptions. Commenters stated that

survey respondents appropriately took time and effort into account when valuing CPT code 92523 but had difficulty using a time-based reference code to value the RVU of an untimed code like CPT code 92523. Commenters noted that the HCPAC acknowledged that the work of the second hour involved in CPT code 92523 is indeed more intense than the first hour. Additionally, commenters stated that the work RVU reduction of CPT code 92524 was arbitrary because it was based solely on intraservice time and failed to recognize the more difficult aspects of performing the service compared to that of CPT code 92522. Commenters requested reconsideration of CPT codes 92523 and 92524 through refinement panel review.

Response: We believe that our interim final work RVU is most appropriate for these services. In the HCPAC recommendation for CPT code 92523 the affected specialty society stated that its survey results were faulty for this CPT code because those surveyed did not consider all the work necessary to perform the service. The commenters did not provide any information that demonstrates that our valuations fail to fully account for the intensity, work, and time required to perform these services. Therefore, we are finalizing our CY 2014 interim final values for CY 2015. We did not refer these codes to refinement because the request did not meet the criteria for refinement.

(20) Percutaneous Transcatheter Closure (CPT code 93582)

As detailed in the CY 2014 final rule with comment period, we reviewed new CPT code 93582. Although the RUC compared this code to CPT code 92941 (percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary), which has a work RVU of 12.56 and 70 minutes of intraservice time, it recommended a work RVU of 14.00, the survey's 25th percentile. We agreed with the RUC that CPT code 92941 is an appropriate comparison code and believed that due to the similarity in

intensity and time that the codes should be valued with the same work RVU. Therefore, we assigned an interim final work RVU of 12.56 to CPT code 93582.

Comment: One commenter disagreed with the work RVU valuation of CPT code 93582 because they believed it did not accurately reflect the intensity of the procedure, particularly in treating infants. The commenter stated that the RUC concluded that a 55 percent work differential exists between performing this service on a child versus an adult - a fact that they stated supports the higher work RVU recommended by the RUC. As a result, the commenter suggests we assign the RUC-recommended work RVU to CPT code 93582. A commenter requested referral to the refinement panel.

Response: We continue to believe that CPT code 92941 is an appropriate comparison code to CPT code 93582 due to similarity in intensity and time and, as a result, the codes should be valued with the same work RVU. Therefore, we are finalizing our CY 2014 interim final work RVU of 12.56 to CPT code 93582 for CY 2015. We did not refer this code to refinement because the request did not meet the criteria for refinement.

(21) Duplex Scans (CPT Codes 93925, 93926, 93880 and 93882)

For CY 2014 we maintained the CY 2013 RVUs for CPT codes 93880 and 93882. We were concerned that the RUC-recommended values for CPT codes 93880 and 93882, as well as our final values 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 and referred the entire family to the RUC to assess relativity among the codes and then 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.

Comment: One commenter questioned why we did not include all duplex scan codes we determined to be part of the family in our original request to the RUC. Another commenter opposed our valuation approach and stated that we should not redefine the codes in this family and that we should reject the RUC recommendations.

Response: The valuations for CPT codes 93880, 93882, 93925, 93926, 93886 and 93888 are included in this year's valuations in section II.G.3.b

(22) Interprofessional Telephone/Internet Consultative Services (CPT Codes 99446, 99447, 99448 and 99449)

In CY 2014 we assigned CPT codes 99446, 99447, 99448, and 99449 a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment). If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled (for example, a telephone call from a hospital nurse regarding care of a patient) because Medicare pays for telephone consultations regarding beneficiary services as a part of other services furnished to the beneficiary.

Comment: A commenter expressed concern that the services covered by codes 99446-99449 were bundled together, and that no RVUs were published for these codes. The commenter observed that CMS compares the services to contact between nurses and patients in justifying its decision to bundle the services in with other work, and stated that this comparison is inappropriate to use regarding consultation between physicians. The commenter also stated that these services are vital in providing specific specialty expertise in areas where timely face-to-face service is not a viable option. The commenter urged that the status of these services be

changed to "Active," or at least "Non-covered," and that the RUC-recommended values for these services be published.

Response: Medicare pays for telephone consultations regarding beneficiary services as part of other services furnished to a beneficiary. As a result, we continue to believe that CPT codes 99446- 99449 are bundled; and we are finalizing the PFS procedure status indicator of B for these codes for CY 2015.

b. Finalizing CY 2014 Interim Direct PE Inputs

i. Background and Methodology

In this section, we address interim final direct PE inputs as presented in the CY 2014 PFS final rule with comment period and displayed in the final CY 2014 direct PE database available on the CMS website under the downloads at http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage.

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. 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 and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the 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.

In the CY 2014 PFS final rule with comment period (78 FR 74242), we addressed the general nature of some of our common refinements to the RUC-recommended direct PE inputs, as well as the reasons for refinements to particular inputs. In the following sections, we respond to the comments we received regarding common refinements we made based on established

principles or policies. Following those discussions, we summarize and respond to comments received regarding other refinements to particular codes.

We note that the interim final direct PE inputs for CY 2014 that are being finalized for CY 2015 are displayed in the final CY 2015 direct PE input database, available on the CMS website under the downloads for the CY 2015 PFS final rule at www.cms.gov/PhysicianFeeSched/. The inputs displayed there have also been used in developing the CY 2015 PE RVUs as displayed in Addendum B of this final rule with comment period.

Comment*:* Commenters indicated that it would be helpful to have additional information about the specific rationale used in developing refinements, and specifically requested that CMS provide more information regarding how CMS makes the determination of whether an item is typical.

Response*:* We continually seek ways to increase opportunity for public comment. In response to comments received, we have provided more detailed explanations about refinements made for the CY 2015 interim final direct PE inputs. We recognize that we make assumptions about what is typical, and note that we welcome objective data that provides information about the typical case. We prefer that this information be submitted through the notice and comment rulemaking process. We also refer interested stakeholders to section II.F. of this final rule with comment period, in which we provide extensive discussion of the changes to the process that we are finalizing for valuing new, revised, and potentially misvalued codes.

ii. Common Refinements

(1) 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 times within the intra-service 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 services in which we allocate cleaning time to portable equipment items, because the equipment does not need to be cleaned in the room that contains the remaining equipment items, we do not include that time for the remaining equipment items as they are available for use for other patients during that time. In addition, when a piece of equipment is typically used during any additional visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the pre-service or post-service tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure.

Some commenters have repeatedly objected to our rationale for refinement of equipment minutes on this basis. We acknowledge the comments we received reiterating those objections to this rationale and refer readers to our extensive discussion in response to those objections in

the CY 2012 PFS final rule with comment period (76 FR 73182). In the following paragraphs, we address new comments on this policy.

Comment*:* A commenter indicated that CMS removed minutes assigned to vascular ultrasound rooms for activities that CMS does not believe take place in the room, but CMS did not provide factual support for this assumption. The commenter further stated that CMS did not articulate the connection between the relevant data that the Administrative Procedures Act (APA) requires CMS to consider and the conclusion that CMS reached. The commenter indicated that they conducted a survey of a significant number of providers, in which most providers indicated that they performed these pre-service tasks in the room.

Response*:* We note that we would welcome comments that include vetted survey results, especially where the data are included. Statements regarding the existence of data to support commenters' assertions do not provide us with information to support conclusions based on the data. We acknowledge that we make assumptions about we believe to be typical. If there are data that support or refute these assumptions, we would be interested in reviewing that information. We would be most interested in reviewing survey data that address multiple points of our assumptions regarding high-cost equipment, including how many procedures are furnished in a day, how often the equipment is being used, and other such information.

Comment*:* A commenter stated that CMS should publish, on a quarterly basis, refinements to the equipment times, rather than waiting until the final rule to publish these changes.

Response*:* We appreciate the commenter's concern about our making available timely information about refinements to practice expense inputs. We note that since we do not review and make refinements to practice expense inputs on a quarterly basis, we do not have information to publish on a quarterly basis. Rather, we have reviewed and refined practice

expense recommendations from the RUC on an annual basis for the subset of codes for which recommendations have been provided to us. Because we have received many requests from stakeholders to publish our refinements as proposals in the proposed rule rather than in the final rule, we are finalizing a change in the process in which changes to RVUs and direct PE inputs will be included in the proposed rule rather than first appearing in the final rule with comment period. We refer readers to section II.F. of this final rule with comment period for further information about this change. We believe that this process will address commenters' concerns about having an opportunity to review these changes prior to the publishing of the final rule.

Comment*:* Several commenters asked that CMS identify what constitutes a highly technical piece of equipment.

Response*:* As we have previously indicated, during our review of all recommended direct PE inputs, we consider such items as the degree of specificity of a piece of equipment, which may influence whether the equipment item is likely to be stored in the same room in which the clinical staff greets and gowns, obtains vitals, or provides education to a patient prior to the procedure itself. We would expect that items that are highly specific to particular procedures would be moved between rooms for those procedures. We also consider the level of portability (including the level of difficulty involved in cleaning the equipment item) to determine whether an item could be easily transferred between rooms before or after a given procedure. Items that are portable would also be expected to be moved between rooms. We also examine the prices for the particular equipment items to determine whether the equipment is likely to be located in the same room used for all the tasks undertaken by clinical staff prior to and following the procedure. We believe that highly expensive equipment would not be kept in a location that does not allow for its maximum utilization. For each service, on a case-by-case basis, we look at the description provided in the RUC recommendation and consider the overlap

of the equipment item's level of specificity, portability, and cost; and, consistent with the review of other recommended direct PE inputs, we make the determination of whether the recommended equipment items are highly technical. We note that it is not practical to ensure that all of the existing equipment time in the database is allocated accordingly, but as we review any recommendations received from the RUC, we make this determination. To provide stakeholders with examples of the types of equipment items that are and are not considered highly technical, we have listed several items below and indicated whether they are highly technical.

TABLE 16: Classification of Highly Technical Equipment

Highly Technical			Not Highly Technical		
Item	**CMS Code**	**Price**	**Item**	**CMS Code**	**Price**
room, CT	EL007	$1,284,000.00	Light, exam	EQ168	$1,630.12
accelerator, 6-18 MV	ER010	$1,832,941.00	Table, exam	EF023	$1,338.17
gamma camera system, single-dual head SPECT CT	ER097	$600,272.00	Chair, medical recliner	EF009	$829.03

(2) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the pre-service, service period, and post-service 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 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 to determine their appropriateness. When we do not accept the RUC-recommended exceptions , we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases

when a service is typically billed with an E/M, 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." In these instances, CMS staff reviews these tasks to determine whether they are similar to tasks delineated for other services under the PFS. For those tasks that do not meet this criterion, we do not accept those clinical labor tasks as direct inputs.

(3) Equipment Minutes for Film Equipment Inputs

In section II.A. of this final rule with comment period, we finalize our proposal to accept the RUC recommendation to remove inputs associated with film technology that are associated with imaging services. We acknowledge comments received regarding the minutes allocated to equipment items associated with film technology; we will not address those comments below, because subsequent to the publication of the CY 2014 final rule with comment period, as discussed in section II.A. of this final rule with comment period, we finalized our proposal to remove these inputs from the Direct PE database, and thus the comments are no longer relevant.

(4) Standard Inputs for Moderate Sedation

In establishing interim final direct PE inputs for services that contain the standard moderate sedation input package, we refined the RUC's recommendation by removing the stretcher (EF018) and adjusting the standard moderate sedation equipment inputs to conform to the standard moderate sedation equipment times. These procedures are listed in Table 17.

Comment*:* Commenters objected to our refinement of the standard moderate sedation equipment input times to conform to the moderate sedation equipment standard times, since it decreased the time allocated to these equipment items.

Response*:* We note that for moderate sedation procedures, the equipment time is tied to

the RN time rather than to the entire service period. Specifically, this time includes 2 minutes for sedate/apply anesthesia, 100 percent of physician intraservice time, and 60 minutes of post-procedure time for every 15 minutes of RN monitoring time. The times included in Table 17 reflect this standard. We note that for all procedures in Table 17 the times allocated to the equipment items that were interim final for 2014 were already consistent with the moderate sedation standard equipment times, with the exception of CPT code 37238, which was mistakenly allocated 257 minutes, when the correct time is actually 242 minutes.

Comment*:* Commenters indicated that for office endoscopic procedures, the stretcher is typically used throughout the entire procedure, as well as during post-procedure monitoring. Other commenters indicated that the stretcher is required during the moderate sedation recovery time. The commenters requested that we include the stretcher for those procedures, and that we reduce the increased time allocated to the power table.

Response*:* In section II.A. of this final rule with comment period, we finalized our proposal to modify the standard moderate sedation input package to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. We indicated that the revised package would be applied to relevant codes as we review them through future notice and comment rulemaking. We have therefore refined those inputs to incorporate the stretcher for these codes listed in Table 17. Since we are incorporating the stretcher, we have removed the power table for procedures in which a power table was previously included. We will hold these procedures as interim final for CY 2015 due to the insertion of the stretcher and removal of the power table.

We are therefore finalizing the PE inputs for the procedures containing the standard moderate sedation inputs, with the additional refinements of including the stretcher for all of these procedures, removing the power table for the codes noted in Table 17 as containing a

power table, and adjusting the equipment time for CPT code 37238. We note that these changes are displayed in the final CY 2015 direct PE input database, available on the CMS website under the downloads for the CY 2015 PFS final rule at www.cms.gov/PhysicianFeeSched/.

TABLE 17: CPT Codes with Stretcher Added

CPT Code	Short Descriptor	Moderate Sedation	Contained Power Table?
10030	Guide cathet fluid drainage	152	
36245	Ins cath abd/l-ext art 1st	167	
37236	Open/perq place stent 1st	332	
37238	Open/perq place stent same	242	
37241	Vasc embolize/occlude venous	272	
37242	Vasc embolize/occlude artery	342	
37243	Vasc embolize/occlude organ	362	
37244	Vasc embolize/occlude bleed	332	
43200	Esophagoscopy flexible brush	77	Yes
43201	Esoph scope w/submucous inj	80	Yes
43202	Esophagoscopy flex biopsy	82	Yes
43206	Esoph optical endomicroscopy	92	Yes
43213	Esophagoscopy retro balloon	107	Yes
43215	Esophagoscopy flex remove fb	82	Yes
43216	Esophagoscopy lesion removal	84	Yes
43217	Esophagoscopy snare les remv	92	Yes
43220	Esophagoscopy balloon <30mm	82	Yes
43226	Esoph endoscopy dilation	87	Yes
43227	Esophagoscopy control bleed	92	Yes
43229	Esophagoscopy lesion ablate	107	Yes
43231	Esophagoscop ultrasound exam	107	Yes
43232	Esophagoscopy w/us needle bx	122	Yes
43235	Egd diagnostic brush wash	77	Yes
43236	Uppr gi scope w/submuc inj	82	Yes
43239	Egd biopsy single/multiple	77	Yes
43245	Egd dilate stricture	85	Yes
43247	Egd remove foreign body	92	Yes
43248	Egd guide wire insertion	82	Yes
43249	Esoph egd dilation <30 mm	82	Yes
43250	Egd cautery tumor polyp	82	Yes
43251	Egd remove lesion snare	82	Yes
43252	Egd optical endomicroscopy	92	Yes
43255	Egd control bleeding any	92	Yes
43270	Egd lesion ablation	107	Yes
43450	Dilate esophagus 1/mult pass	77	Yes
43453	Dilate esophagus	87	Yes
49405	Image cath fluid colxn visc	162	
49406	Image cath fluid peri/retro	162	
49407	Image cath fluid trns/vgnl	167	

(5) Recommended PE Inputs Not Used in the Calculation of Practice Expense Relative Value Units

In preparing the Direct Practice Expense Input database for CY 2014, we noted that in some cases, there were recommended inputs in the database that were not used in the calculation of the PE RVUs. In cases where inputs are included for a particular service in a particular setting, but that service is not priced in that setting, the inputs are not used. In the documentation files for the CY 2014 final rule, we stated, "In previous years, we have displayed recommended inputs even when these inputs are not used in the calculation of the practice expense relative value units. We note that we are no longer displaying such inputs in these public use files since they are not used in the calculation of the practice expense relative value units that appear in the final rule."

Comment*:* Some commenters objected to our removing practice expense inputs for services that were not reviewed for CY 2014.

Response*:* As indicated in the documentation files, the inputs removed were not used in the calculation of the PE RVUs. Therefore, their removal has no impact on the PE RVUs for these services or the payment for services. We remind readers that, from our perspective, the sole purpose of the Direct PE database is to establish PE RVUs. We believe it is more transparent for these inputs to not appear in the Direct Practice Expense Input database when they do not contribute to the PE RVU calculation for the relevant services.

iii. Code-Specific Direct PE Inputs

We note that we received many comments objecting to refinements made based on "CMS clinical review" (including our determination that certain recommended PE inputs were duplicative of others already included with the service), statutory requirements, or established principles and policies under the PFS. We note that for many of our refinements, the specialty

societies that represent the practitioners who furnish the service objected to most of these refinements for the general reasons described above or for the reasons we respond to in the "background and methodology" portion of this section, or stated that they supported the RUC recommended PE inputs. Below, we respond to comments in which commenters address specific CPT/HCPCS codes and explain their objections to our refinements by providing us with new information supporting the inclusion of the items and/or times requested. When discussing these refinements, rather than listing all refinements made for each service, we discuss only the specific refinements for which commenters provided supporting information. We indicate the presence of other refinements by noting "among other refinements" after delineating the specific refinements for a particular service or group of services. For those comments that stated that an item was "necessary for the service" and provided no additional rationale or information, we conducted further review to determine whether the inputs as refined were appropriate and concluded that the inputs as refined were indeed appropriate. We also note that in many cases, commenters objected to our indication that items were duplicative, stating that they did not know where the duplication existed. In future rulemaking, we do not intend to respond to comments where the commenters dispute the duplicative nature of inputs unless commenters specifically explain why the relevant items are not duplicative with the identical items included in a room, kit, pack, or tray. We expect that commenters will review the components of the room, kit, pack, or tray included for that procedure prior to commenting that the item is not duplicative. Finally, we note that in some cases we made proposals related to comments received in response to the CY 2014 final rule with comment period. In cases where we have addressed the concerns of commenters in the proposed rule, we do not respond to comments here as well.

(1) Cross-Family Comments

Comment: We received comments regarding refinements to equipment times for many

procedures for which commenters indicated that the equipment time for the procedure should include the time that the equipment is unavailable for other patients, including while preparing equipment, positioning the patient, assisting the physician, and cleaning the room. Commenters also requested that we indicate which clinical labor tasks should be included in calculating the equipment time for highly technical equipment.

Response*:* As stated above, we agree with commenters that the equipment time should include the times within the intra-service period when a clinician is using the piece of equipment plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. We believe that some of these commenters are suggesting that we should allocate the full number of clinical labor minutes included in the service period to the equipment items. However, as we have explained, the clinical labor service period includes minutes based on some clinical labor tasks associated with pre- and post-service activities that we do not believe typically preclude equipment items from being used in furnishing services to other patients because these activities typically occur in other rooms. The equipment times allocated to the CPT codes in Table 18 already include the full intraservice time the equipment is typically used in furnishing the service, plus additional minutes to reflect time that the equipment is unavailable for use in furnishing services to other patients. In response to commenters request for clarification, Table 19 lists the standard clinical labor tasks to be included in the calculation of time allocated to highly technical equipment. We note that in some cases, some specialized intraservice clinical labor tasks are also included in the equipment time calculations; we have not detailed every possible case in this table.

TABLE 18: Equipment Inputs that Include Appropriate Clinical Labor Tasks About Which Comments Were Received

CPT Code	Equipment Items
70551	EL008
70552	EL008
70553	EL008
93880	EL016
93882	EL016

TABLE 19: Clinical Labor Tasks Included in Calculation of Equipment Time for Highly Technical Equipment.

Clinical Labor Task
Prepare room, equipment, supplies
Prepare and position patient
Assist physician in performing procedure and/or Acquire images
Clean room/equipment by physician staff
Technologist QC's images in PACS, checking for all images, reformats, and dose page

Comment*:* We received comments regarding refinements to clinical labor times for several procedures, in which commenters indicated that CMS reduced the clinical labor minutes inappropriately for tasks related to film inputs, since the recommended minutes were based on the PEAC surveyed times. Tasks included "Process images, complete data sheet, present images and data to the interpreting physician" and "Retrieve prior appropriate imaging exams."

Response*:* The surveyed times referenced by the commenters refer to the clinical labor tasks associated with film technology. In reviewing the times associated with these clinical labor tasks, we noted that it would be consistent with our policy finalized in this rule to adjust the times associated with clinical labor tasks for all interim final codes to be consistent with the RUC recommendations regarding clinical labor tasks for digital technology. We are making the associated changes and holding these direct PE inputs interim final for 2015. These clinical labor tasks associated with film and digital inputs are presented side-by-side, along with the range of typical times, in Table 20. The specific interim final codes and their time changes are

listed in Table 21.

TABLE 20: Clinical Labor Tasks Associated with Digital Technology

Service Period	Clinical Labor Task: Film Inputs	Typical Minutes	Clinical Labor Task: Digital Inputs	Typical Minutes
Pre-Service	Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD / Retrieve Prior Image for Comparison	4 to 7	Availability of prior images confirmed	2
			Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2
Service Period: Post-Service	Process Images, complete data sheet, present images and data to the interpreting physician / Process films, hang films and review study with interpreting MD prior to patient discharge	4 to 20	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

TABLE 21: Interim Final Codes with Adjusted Clinical Labor Times Due to Film-to-Digital Migration

CPT Code	CMS Code	Total Film Task Time (2014)	Total Digital Task Time	Time Change
19081	L043A	8	9	1
19082	L043A	5	5	0
19083	L051B	8	9	1
19084	L051B	5	5*	0
19085	L047A	8	9	1
19086	L047A	5	5*	0
19281	L043A	8	9	1
19282	L043A	5	5*	0
19283	L043A	8	9	1
19284	L043A	5	5*	0
19285	L051B	8	9	1
19286	L051B	5	5*	0
19287	L047A	8	9	1
19288	L047A	5	5*	0
19281	L043A	5	5	0
19282	L043A	5	5	0
70450	L046A	10	9	-1
70460	L046A	11	9	-2
70470	L046A	13	9	-4
70551	L047A	6	9	2
70552	L047A	8	9	0
70553	L047A	8	9	0
72141	L047A	14	9	-5
72142	L047A	16	9	-7
72156	L047A	18	9	-9
72146	L047A	14	9	-5
72147	L047A	16	9	-7
72157	L047A	18	9	-9
72148	L047A	14	9	-5
72149	L047A	16	9	-7
72158	L047A	18	9	-9
74174	L046A	27	9	-22

*Add-on codes are allocated fewer minutes for these activities.

(2) Code-Specific Comments

(a) Destruction of Premalignant Lesions (CPT Codes 17000, 17003, 17004)

In establishing interim final direct PE inputs for CY 2014, CMS accepted the RUC's

recommendations for supply item LMX 4% anesthetic cream (SH092).

Comment*:* Commenters indicated that the quantity of cream units in CPT code 17003 created a rank order anomaly with CPT codes 17000 and 17004, and that the inclusion of 3 grams was incorrect. Instead, 1 gram should have been included in CPT code 17003.

Response*:* We agree with the commenters that the quantity of SH092 in 17003 should be 1 gram. However, we also note that CPT code 17000 should also contain a quantity of 1 gram in order to avoid the rank order anomaly. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 17000, 17003, and 17004, with the additional refinement of changing the quantity of SH092 to 1 for CPT codes 17000 and 17003.

(b) Breast Biopsy (CPT Codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 19085, 19086, 19287, and 19288 by removing several new PE inputs, including items called "20MM handpiece—MR,'' ''vacuum line assembly,'' ''introducer localization set (trocar),'' and ''tissue filter,'' since we concluded that these items served redundant clinical purposes with other biopsy supplies already included in the PE inputs for these codes. We also removed three new equipment items, described as ''breast biopsy software,'' ''breast biopsy device (coil),'' and "lateral grid," because we determined that these items served clinical functions to items already included in the MR room.

Comment*:* Commenters indicated that the vacuum assisted breast biopsy requires an assisted biopsy needle system, and tubing must be run from the biopsy device to the biopsy control unit. Commenters also discussed supply items "introducer localization set (trocar)" and "tissue filter," stating that the trocar is used to target the biopsy on the correct lesion, and the

tissue filter is necessary to remove the collected core samples from the collection chamber. Commenters described the importance of the "breast biopsy device (coil) ," which is used to move one breast out of the way and the "breast biopsy software," which is required to make the necessary calculations to target and biopsy the lesions. Finally, commenters stated that the lateral grid is necessary to place the trocar correctly.

Response*:* The equipment item "breast biopsy device w-system (Mammotome)" (EQ074) is described as "an all-in-one platform designed for use under ultrasound, MRI, stereotactic and 3D image guidance" and is used with supply item "Mammotome probe" (SD094). Therefore, the supply items "20 MM handpiece, " "vacuum line assembly," "tissue filter," and "trocar," are duplicative of items already included in this procedure. We do note that we have used the invoice to create a price for equipment item "Breast biopsy device (coil)" (EQ371) at a price of $12,238. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 19085, 19086, 19287, and 19288 as established with the additional refinement of incorporating the equipment item "Breast biopsy device (coil)" (EQ371).

Comment*:* A commenter noted that the new breast biopsy codes do not distinguish between the type of biopsy device used for the procedure, and that the cost of using the vacuum-assisted biopsy device (including a Mammotome probe, a Mammotome probe guide, and tubing and vacuum for the Mammotome device) is nearly eight times the cost of the equipment and supplies required to perform a standard (mechanical) core needle biopsy. The commenter noted that vacuum-assisted biopsy devices are predominantly used in stereotactic and MRI-guided breast biopsy procedures and 50 percent of the time in ultrasound-guided breast biopsy procedures.

Response*:* For a discussion about the change in coding, we refer readers to section II.F.

of this final rule with comment period, where we finalize the work RVUs for interim final 2014 codes. With regard to the direct PE inputs for these services, we note that we include direct PE inputs based on the typical case, and since, as the commenter points out, the vacuum-assisted biopsy devices are typically used, we include these items as direct PE inputs.

In reviewing the breast biopsy codes, we noted that we inadvertently included supply and equipment items related to breast biopsies in CPT codes 19283, 19284, 19285, 19286, 19087, and 19088, which are procedures that describe the placement of a localization device, not a biopsy. We will therefore remove the items listed in Table 22, which are currently included as direct PE inputs for these procedures. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288 as established, with the additional refinements noted above.

TABLE 22: Supply and Equipment Items Inadvertently Included in Localization Device Placement Breast Biopsy Codes

CPT	SD034	SC022	EQ074
19283	X		X
19284	X		X
19285			X
19286			X
19087	X	X	X
19088	X	X	X

(c) Nasal/Sinus Endoscopy (CPT Codes 31237, 31238)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 31237 and 31238 by refining the nurse blend (L037D) clinical labor time associated with task "Monitor pt. following service/check tubes, monitors, drains" from 15 minutes to 5 minutes.

Comment*:* Commenters stated that CMS should maintain consistency in the direct PE

inputs across services by allocating the standard 15 minutes for every hour of post-procedure monitoring time. Commenters indicated that monitoring after these procedures is critical, since the risk of recurrent bleeding is high and patients may become lightheaded.

Response*:* There are two types of post-procedure monitoring time; a standard 15 minutes per hour of post-procedure monitoring time for moderate sedation, and a standard 15 minutes per hour of post-procedure monitoring time unrelated to moderate sedation. We understand the commenter's position to mean that there is 60 minutes of post-procedure monitoring required for these services (in accordance with the 15 minutes of RN time per 60 minutes of monitoring). Because these procedures previously included 5 minutes of post-procedure monitoring time, we do not have a reason to believe that the monitoring time would have increased by 55 minutes. Should commenters believe this is the case, we invite commenters to provide information to justify this change. In cases where the specialty society is recommending post-procedure monitoring unrelated to moderate sedation, it is important that the recommendation clearly indicates the reason for the monitoring and the relationship between the clinical staff time and the monitoring time. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 31237 and 31238 as established.

(d) Implantation and Removal of Patient Activated Cardiac Event Recorder (CPT Codes 33282 and 33284)

In the CY 2013 final rule with comment period, in response to nomination of CPT codes 33282 and 33284 as potentially misvalued codes, we indicated that we did not consider the absence of pricing in a particular setting as an indicator of potentially misvalued codes. However, we requested that the RUC review these codes, including the work RVUs, for appropriate nonfacility and facility inputs.

Comment*:* A commenter expressed disappointment that CMS did not price these services in the nonfacility setting but did not provide further information about this decision.

Response*:* We received recommendations from the RUC for CPT codes 33282 and 33284 that did not include nonfacility inputs. Stakeholders who are interested in providing information about the direct PE inputs used in furnishing these services are welcome to submit this information to us; information about the level of information we seek is available to stakeholders in the sample PE worksheet available on the CMS website under downloads at http://www.cms.gov/PhysicianFeeSched/PFSFRN/list.asp#TopOfPage. We encourage commenters to submit the best data available on the appropriate inputs for these services.

(e) Transcatheter Placement of Intravascular Stent (CPT Codes 37236, 37237)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 37236 and 37237 by including supply item "catheter, balloon, PTA" (SD152) as a proxy for "balloon expandable" because we believed that was an appropriate proxy. The invoices provided with the recommendation did not indicate the items on the PE worksheet with which they were associated.

Comment*:* The specialty society representing practitioners who furnish these services indicated that the item "balloon expandable" actually referred to a "balloon implantable stent," and that the invoices provided were associated with that item.

Response*:* We acknowledge the specialty society's clarification of the RUC recommendation. We will add item "balloon implantable stent" at a price of $1,500, and remove the proxy item SD152. We note that when line items on the invoices provided are not clearly labeled, it is often difficult for us to determine how to relate the items on the PE spreadsheet with the items on the invoices. For specialty societies to ensure that the requested items are considered for inclusion in the relevant procedure codes, it is important that invoices accompany the RUC

recommendations and the line items associated with items on the PE spreadsheet are clearly labeled.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 37236 and 37237 as established with the additional refinement of including "balloon implantable stent" and removing "catheter, balloon, PTA" (SD152).

(f) Esophagoscopy (CPT Codes 43197 and 43198)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43197 and 43198 to remove the Medical/Technical Assistant (L026A) time associated with clinical labor task "Clean Surgical Instrument Package," since no surgical instrument package is included in the service, and to remove the endoscopic biopsy forceps (SD066) from CPT code 43198, among other refinements.

Comment*:* Commenters acknowledged that the procedure did not contain a surgical instrument package, but stated that the time was still necessary for cleaning equipment, such as the nasal speculum, bayonette forceps, and biopsy forceps.

Response*:* In general, as a matter of relativity throughout the PFS, the time allocated for the standard clinical labor task "Clean room/equipment following procedure" encompasses time for cleaning all equipment items. The only exceptions to this rule are for equipment items that are tied to specific clinical labor tasks, such as cleaning the surgical instrument pack or cleaning a scope. We do not believe it would serve relativity to separately break out time to clean various different types of equipment.

For the biopsy forceps, we indicated in the final rule with comment period that the information included with the RUC recommendation suggested that the biopsy forceps was reusable (as suggested by the cleaning time mentioned in this comment). As such, we have

created a new equipment item based on the invoice provided with the recommendation and assigned 46 minutes to this equipment item. However, since we did not receive a paid invoice with this item, we will price it at $0 until we receive a paid invoice.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 43197 and 43198 as established, with the additional refinement of including 46 minutes for the reusable biopsy forceps.

(g) Esophagoscopy/Esophagoscopy Gastroscopy Duodenoscopy (EGD) (CPT Codes 43200, 43201. 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, 43270)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43200, 43201. 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, and 43270 by refining the quantity of item "canister, suction" (SD009) from 2 to 1.

Comment*:* Commenters indicated that, for patient safety reasons, one suction canister is needed for the mouth, and another for the scope for patient safety reasons. Other stakeholders, specifically, several specialty societies with whom we met during the comment period, informed us that one suction canister is sufficient and typical for these services.

Response*:* We are persuaded by the information provided by the medical specialty societies during the comment period who indicated that one suction canister is typical.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43201 by removing needle, micropigmentation (tattoo) (SC079), as the needle required for this procedure needs to go through an endoscope, and no invoice was provided for this item.

Comment*:* Commenters indicated that the tattoo needle was required to mark the site for injection.

Response*:* We did not receive an invoice for the tattoo needle and have no information about this item. We are also unable to include this item in the PE calculations without a method to price it. We do not believe that we have a reasonable proxy at this time. If we receive invoices for this item, we will be able to include it in the direct PE input database.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43201, 43220, 43226, and 43231 by removing supply item "cup, biopsy-specimen non-sterile 4oz" (SL035).

Comment*:* Commenters indicated that the endoscopy base code, 43200, is included in all of these procedures. Since the biopsy cup is included in the endoscopy base code, it should be included for these codes as well.

Response*:* We agree with commenters that it is appropriate to include this supply item for these procedures. We will include the supply item "cup, biopsy-specimen non-sterile 4oz" in the direct PE inputs for these procedures.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 43220 by substituting supply item "SD019" as a proxy for "SD025."

Comment*:* Commenters requested that we include "endoscopic balloon, dilation" (SD287) rather than a proxy, as this supply item is now included in the database.

Response*:* After receiving clarification regarding this request, we agree with commenters that SD287 is an appropriate supply input for this procedure. Therefore, we will include SD287 for CPT code 43220.

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's

recommendations for CPT codes 43220, 43249, and 43270 by removing supply item "guidewire, STIFF" (SD090), among other refinements.

Comment*:* Commenters indicated that the guidewire is required to safely straddle tumors for which there is impaired visibility and an inability to pass the scope through.

Response*:* We agree with commenters that it would be appropriate to include supply item "guidewire – STIFF" in these procedures. We will include the supply item "guidewire – STIFF" in the direct PE inputs for these procedures.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for codes 43200, 43201. 43202, 43206, 43215, 43216, 43217, 43220, 43226, 43227, 43231, 43232, 43235, 43236, 43239, 43245, 43247, 43248, 43248, 43250, 43251, 43252, 43255, and 43270 as established, with the additional refinements of including the supply items noted above.

(h) Dilation of Esophagus (CPT Codes 43450, 43453)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 43450 and 43453 by removing equipment item "endoscope disinfector, rigid or fiberoptic, w-cart" (ES005), and not creating a new item "mobile stand, vital signs monitor," and other refinements.

Comment*:* Commenters stated that the endoscope disinfector is a necessary part of all endoscopic procedures for sanitary and safety reasons, and that it should be restored for all gastrointestinal endoscopy codes. Commenters also noted that the mobile stand is the standard method of monitoring that must be moved along with the patient.

Response*:* Since these are non-endoscopic dilation codes, there is no scope to clean, and thus the endoscope disinfector is unnecessary. The standard inputs for moderate sedation as recommended by the RUC were included in this procedure; the mobile stand overlaps with the

standard moderate sedation input items. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for codes CPT codes 43450 and 43453 as established.

(i) Spinal Injections (CPT Codes 62310, 62311, 62318, 62319)

In establishing interim final direct PE inputs for CY 2014, CMS accepted the RUC recommendations for CPT codes 62310, 62311, 62318, and 62319. Based on comments received, we made a proposal to maintain the CY 2014 direct PE inputs for CY 2015 while the codes are reexamined for bundling. We are finalizing this proposal, so while we acknowledge comments received on these codes, we will not respond to these comments as the interim final inputs to which the comments relate will not be used for 2015.

(j) Percutaneous Implantation of Neurostimulator (CPT Code 63650)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code time by removing the time associated with clinical labor task "Clean Surgical Instrument Package" and removing supply item "pack, cleaning, surgical instruments" (SA043) since no surgical instrument package is included in the service.

Comment*:* Commenters indicated that clinical staff time is critical for the safety and efficiency of the procedure, and that the surgical instrument cleaning package is necessary to ensure proper adherence of the electrodes.

Response*:* In general, as a matter of relativity throughout the PFS, the time allocated for the standard clinical labor task "Clean room/equipment following procedure" encompasses time for cleaning all equipment items. The only exceptions to this rule are for equipment items which are tied to specific clinical labor tasks, such as cleaning the surgical instrument pack or cleaning a scope. We do not believe it would serve relativity to separately break out time to clean various different types of equipment. After consideration of the comments received, we are finalizing

the CY 2014 interim final direct PE inputs for CPT code 63650 as established.

(k) Chemodenervation (CPT Codes 64616, 64642, 64644, 64646, 64647)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 64616, 64642, 64644, 64646, and 64647 by reducing the minutes allocated to "table, exam" (EF023) and removing the time associated with clinical labor task "Complete botox log," as well as reducing the L037D time for clinical labor "assist physician performing procedure" for CPT code 64616, among other refinements.

Comment*:* One commenter opposed our adjusting the minutes allocated to the exam table. Commenters stated that the reference code, 64615, included three minutes of clinical labor time for "complete botox log," and requested that they be included since they are in the reference code. One commenter asked whether CMS planned to remove the minutes from the reference code as well. Other commenters indicated that as with most injections, it is necessary to document various elements of information for safety purposes.

Response*:* Upon reviewing the time allocated to the exam table, we noted that our standard equipment policy is to allocate the entire service period for equipment that is not highly technical. Therefore, we will allocate minutes for the entire service period for the exam table, as follows: 28 minutes for 64616, 44 minutes for 64642, 49 minutes for 64644, 44 minutes for 64646, and 49 minutes for 64647. We appreciate commenters pointing out the three minutes of time inadvertently allocated for "complete botox log" in the reference code, 64615, and will consider this issue in future rulemaking. We note that one of the benefits of having information stored in the direct PE database at the clinical labor task level is that it allows us to make comparisons of codes under review to existing codes in the PE database. This will help us ensure greater consistency in our refinements. As commenters point out, various injections are documented in logs, rather than medical records. The use of a different location for

documentation is not a reason to allocate additional clinical labor time for a particular service.

Comment*:* One commenter supported our adjustment of "assist physician" time from 7 minutes to 5 minutes. Another commenter disagreed with the refinement and requested that CMS explain how physician time was calculated, while a different commenter stated that the "assist physician" time should be 28 minutes.

Response*:* Upon reviewing the work time and the time allocated for assist physician, we determined that 7 minutes is actually appropriate for the assist physician task.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 64616, 64642, 64644, 64646, and 64647 as established, with the additional refinement of adjusting the minutes for the exam table as indicated above and adding 2 minutes of clinical labor for the "assist physician" task for 64616.

(l) MRI Brain (CPT Codes 70551, 70552, 70553)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 70551, 70552, and 70553 by adjusting the time for clinical labor task "assist physician in performing procedure/acquire images," removing 2 minutes of clinical labor time for clinical labor task "escort patient from exam room due to magnetic sensitivity," removing supply items "gauze,sterile 2in x 2in" (SG053), "tape, phix strips (for nasal catheter)" (SG089), "povidone swabsticks (3 pack uou" (SJ043), and "swab-pad, alcohol" (SJ 053) from CPT codes 70552 and 70553, among other refinements.

Comment*:* Commenters indicated that the times associated with clinical labor task "assist physician in performing procedure/acquire images" reflected the PEAC surveyed times, and they had no reason to believe that the time had decreased since the PEAC review.

Response*:* As indicated in the PFS CY 2014 final rule with comment period (78 FR 74345), the procedure time for these services was last reviewed in 2002. We noted that we

believe there should be no significant difference between the time to acquire images for an MRI of the brain and an MRI of the spine, and that, rather than rely on very old survey data, it would be appropriate to crosswalk the time associated with the MRI of the spine to the MRI of the brain. We continue to believe that this time is more accurate than that of the survey data.

Comment*:* Commenters noted that the clinical labor task "escort patient from exam room due to magnetic sensitivity" is a necessary activity for patient safety.

Response*:* Upon review of this clinical labor task, we noted that this task was included in the PE worksheets from when these codes were previously reviewed in 2002. Therefore, since this activity does not reflect a newly added clinical labor task, we agree with commenters that it would be appropriate to include 2 minutes for this clinical labor task.

Comment*:* Commenters stated that the supplies removed from CPT codes 70552 and 70553 were necessary supplies for the service, and that the specialty society incorrectly included supply item "tape, phix strips (for nasal catheter)" (SG089), when the correct supply item was "tape, surgical paper 1in (Micropore)" (SG079).

Response*:* We note that these supplies were removed because they were already contained in the supply item "kit, IV starter" (SA019). Table 23 shows the items contained in the IV starter kit and the corresponding supply items removed due to redundancy.

TABLE 23: Items Removed for Redundancy and Parallel Items Included in IV Starter Kit

Items in IV starter kit	Corresponding Items Removed for Redundancy
1 tourniquet	-
1 PVP ointment	povidone swabsticks (3 pack uou)
1 PVP prep pad	swab-pad, alcohol
2 gauze sponges	gauze, sterile 2in x 2in
1 bandage (1"x3")	-
1 sm roll surgical tape	tape, surgical paper 1in
1 pr gloves	-
1 underpad 2ft x 3ft (Chux)	-

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 70551, 70552, and 70553, with the additional refinement of including 2 minutes of clinical labor time as noted above.

(m) MRI Spine (CPT Codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, 72158)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, and 72158 by removing 2 minutes of clinical labor time for clinical labor task "escort patient from exam room due to magnetic sensitivity," and other refinements.

Comment*:* Commenters noted that the clinical labor task "escort patient from exam room due to magnetic sensitivity" is a necessary activity for patient safety.

Response*:* Upon review of this clinical labor task, we noted that this task was included in the PE worksheets from when these codes were previously reviewed in 2002. Therefore, since this activity does not reflect a newly added clinical labor task, we agree with commenters that it would be appropriate to include 2 minutes for this clinical labor task.

Comment*:* A commenter noted that CMS did not include a contrast imaging pack, which includes supplies necessary for contrast enhanced studies.

Response: In section II.B. of this final rule with comment period, we finalized our policy to add a contrast imaging pack to be used for imaging services with contrast. Therefore, we will include the contrast supply pack (CMS code SA114) for CPT codes 72142, 74147, 72149, 72156, 72157, and 72158.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 72141, 72142, 72146, 72147, 72149, 72156, 72157, and 72158, with the additional refinement of including 2 minutes of clinical labor time and including the supply pack for the services noted above.

(n) Selective Catheter Placement (CPT Code 75726)

In establishing interim final direct PE inputs for CY 2014, when reviewing CPT code 36245, which was identified through a misvalued code screen of codes reported together more than 75 percent of the time, we noted that it was frequently billed with 75726. We then noted that these two services had identical time for "assist physician in performing procedure," and since the time for 36245 was reduced from 73 to 45 minutes, refined the clinical labor time for 75726 to correspond to this change.

Comment: Commenters indicated that the 73 minutes reflected the PEAC surveyed times, and that these activities are imaging-related, and in addition to the time and activities inherent in the accompanying surgical base code.

Response: As indicated elsewhere in this section, we note that the PEAC survey data are very old, and that refinements based on more updated information are appropriate. We continue to believe that it is appropriate for the intraservice times for 36245 and 75726 to continue to correspond to one another, as they are frequently furnished together. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 75726 as established.

(o) Radiation Treatment Delivery (CPT Codes 77373, 77422, 77423)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77373 by refining the equipment time for "pulse oximeter w-printer" (EQ211) and "SRS system, SBRT, six systems, average" (ER083) to conform to established equipment policies.

Comment*:* Commenters stated that the times should be maintained at 104 minutes, rather than being reduced to 86 minutes, and indicated the clinical labor task lines that should be included in the calculations.

Response*:* Upon reviewing the equipment times associated with this procedure, we agree with commenters that the time allocated for the equipment should include the time associated with the indicated clinical labor tasks for these equipment items. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 77373 as established, with the additional refinement of adjusting the equipment times to 104 minutes as noted above.

For CY 2014, we also eliminated several anomalous supply inputs included in the direct PE database, which affected 77422 and 77423, among other services.

Comment*:* Commenters indicated that upon reviewing the inputs for these services, they noted that the Record and Verify System and the laser targeting system were missing in both of these services, despite being in the original 2005 recommendation.

Response*:* We appreciate the commenters' attention to detail. However, as indicated elsewhere, we do not believe that the record and verify system is medical equipment used in furnishing the technical component of the service. We refer readers to our discussion of this issue in the PFS 2014 Final rule with Comment period (78 FR 74317). Further, since these codes have not been reviewed in many years, we do not know if the laser targeting system

continues to be an appropriate input for these services. Therefore, we request that the RUC examine the inputs for these services to ensure their accuracy.

(p) Hyperthermia (CPT Code 77600)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77600 by refining the time allocated to equipment item "hyperthermia system, ultrasound, external" (ER035) and removing the time associated with clinical labor task "clean scope," among other refinements.

Comment*:* Commenters indicated that the appropriate lines were not used to calculate the recommended equipment times, including cleaning the scope and check dressing.

Response*:* Upon reviewing the comments, we re-examined the equipment time calculation and continue to believe that the time allocated to this equipment item is appropriate. We note that there is no scope used in this procedure, so time to clean the scope is unnecessary. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 77600 as established.

(q) High Dose Rate Brachytherapy (CPT Codes 77785, 77586, 77787)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 77785, 77786, and 77787 to remove "Emergency service container – safety kit," as we consider it an indirect PE.

Comment*:* Commenters noted that the emergency container is a safety device used when a source must be retrieved manually. Commenters indicated that it is a mobile item and that the service cannot be provided unless it is in the room, and thus it is a direct PE, since it is directly assumed by a physician in the course of providing the service. Commenters asked that we reclassify this item as a direct input.

Response*:* In our clinical review, we reviewed the work vignettes for these procedures, which did not include the use of the "emergency service container - safety kit" as a part of the procedure. Although we acknowledge that the emergency service container safety kit needs to be readily available during the procedure, we note that "standby" equipment, or items that are not used in the typical case, are considered indirect costs. For further discussion of this issue, we refer readers to our discussion of "standby" equipment in the CY 2001 PFS proposed rule (65 FR 44187).

When reviewing the interim final direct PE inputs for these services, we noted that the specialty societies conducted a survey of the technicians, which revealed higher procedure times than the current procedure times. However, since the RUC indicated that they did not have "compelling evidence," the specialty society did not request the higher procedure times. We believe that if the specialty society believes that the code is undervalued relative to the expert panel value, and there is no indication that the survey was flawed, the specialty society should recommend the use of the surveyed procedure times. In doing so, the specialty society would give CMS the opportunity to consider the information provided alongside the RUC recommended times. We believe that surveys of technicians have the potential to be more accurate, rather than less accurate, than those of physicians, as the technicians do not have incentives to increase the surveyed time. We suggest that rather than attempting to insert items that are not standard in the PE methodology, that specialty societies make a strong, data-driven case, for why the survey times are correct.

Comment: A commenter noted that there have been significant reductions to these CPT codes over the last several years, and urged CMS to phase in the reductions over time should the reductions be deemed appropriate after review of the methodology and data.

Response*:* We note that reductions to CPT codes are made on the basis that they are potentially misvalued. We do not typically transition such reductions. However, the Protecting Access to Medicare Act (PAMA) requires that beginning in 2017, CMS transition code-level reductions of greater than or equal to 20 percent in a given year; therefore, beginning in 2017, such reductions will be transitioned.

After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 77785, 77786, and 77787 as established.

(r) Cytopathology (CPT Code 88112)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 88112 by removing the clinical labor time associated with several clinical labor tasks, including "Order, restock, and distribute specimen containers with requisition forms," "Perform screening function (where applicable)," "Confirm patient ID, organize work, verify and review history," and "Enter screening diagnosis in laboratory information system, complete workload recording logs, manage any relevant utilization review/quality assurance activities and regulatory compliance documentation and assemble and deliver slides with paperwork to pathologist."

Comment*:* Commenters pointed out that CPT code 88112 was inadvertently listed in Table 28 in the CY 2014 final rule with comment period as being unrefined by CMS. Commenters also opposed the reductions in clinical labor time, and noted that the PE subcommittee thoroughly reviewed these inputs.

Response*:* We apologize for the inadvertent inclusion of CPT code 88112 in Table 28 of the CY 2014 final rule with comment period. We re-examined the clinical labor tasks in light of the comments received and noted that the clinical labor task "Order, restock, and distribute specimen containers with requisition forms" is not a clinical labor task associated with furnishing

a service to a particular patient, and is therefore allocated in the indirect practice expense. Clinical labor task "Perform screening function (where applicable)" is not a task completed in the typical service, and is therefore not included. Further, clinical labor task "Confirm patient ID, organize work, verify and review history" is subsumed within clinical labor task "Remove slide from coverslipper; confirm patient ID, organize work, send slides to cytotech for screening"; including both would therefore be duplicative. Clinical labor task "Enter screening diagnosis in laboratory information system, complete workload recording logs, manage any relevant utilization review/quality assurance activities and regulatory compliance documentation and assemble and deliver slides with paperwork to pathologist" involves quality assurance activities. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74308) for a discussion regarding quality assurance activities. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 88112.

Comment*:* One commenter noted that the refinements to the PE inputs for CPT code 88112 resulted in a rank-order anomaly, as CPT code 88108 has higher PE RVUs than CPT code 88112, while CPT code 88108 is a less complex service than CPT code 88112. Specifically, commenters stated that it is illogical for a cytology specimen processing technique that involves an additional step that requires materially more resources to have an RVU that is less than an associated technique that requires fewer resources, and expressed concerns about the potential for misreporting.

Response*:* We appreciate this commenter bringing this rank order anomaly to our attention. As indicated in section II.B. of this final rule with comment period, we are referring this code to the RUC as potentially misvalued based on the information received from the commenter.

(s) Duplex Scans (CPT Codes 93880 and 93882)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 93880 and 93882 by removing the equipment time allocated for equipment items "video SVHS VCR (medical grade)" (ED034) and "video printer, color (Sony medical grade)" (ED036), and refining the equipment time for "computer desktop, w-monitor" (ED021) from 68 to 51 minutes, among other refinements.

Comment*:* Commenters indicated that these items are not redundant and asked that CMS explain which items encompass ED034 and ED036. Commenters also stated that the desktop computer is used for the entire intraservice period. Commenters also stated that the refinements were expressed as a final decision effective January 1, 2014.

Response*:* The equipment item "room, vascular ultrasound" (EL016) contains "room, ultrasound general" (EL015), which contains both "video SVHS VCR (medical grade)" and "digital printer (Sony UPD21)." We also note that the RUC has reviewed these codes again for 2015; we refer readers to section II.F. of this rule for further discussion, including the new interim final inputs established for 2015. We further note that contrary to the commenters' assertion, the refinements made were indeed effective January 1, 2014, but were not final decisions; rather, they were interim final for 2014 and subject to public comment.

(t) Electroencephalogram (CPT Codes 95816, 95819, 95822)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 95816, 95819, and 95822 by refining the equipment time allocated to equipment item "EEG, digital, testing system (computer hardware, software & camera)" (EQ330), among other refinements.

Comment*:* Commenters indicated that various staff activities are performed on the computer and requested that we restore the time previously removed.

Response*:* Upon reviewing comments regarding the equipment time, we agree with commenters that we should allocate the entire service period for EQ330, since it is not highly technical equipment. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT codes 95816, 95819, and 95822 as established, with the additional refinement of assigning the intraservice time to EQ330.

(u) Anogenital Examination With Colposcopic Magnification in Childhood for Suspected Trauma (CPT Code 99170)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes, we accepted the RUC's recommendation to include a new clinical labor type called "child life specialist."

Comment: One commenter supported the inclusion of clinical labor staff time for the child life specialist.

Response: We appreciate the commenter's support for this decision. After consideration of the comments received, we are finalizing the CY 2014 interim final direct PE inputs for CPT code 99170 as established.

(v) Immunohistochemistry (HCPCS Codes G0461 and G0462)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT codes 88342 and 88343 by creating G-codes G0461 and G0462 and refining the inputs for these services. We acknowledge comments regarding the refinements CMS made to these inputs, as well as comments indicating that the direct practice expense inputs for these procedures implied that the reporting would be different than the reporting implied by the code descriptors. We note that the RUC has subsequently reviewed CPT codes 88342 and 88343 again and we present the interim final values for 2015 in this final rule with comment

period. Therefore, we will not address specific comments regarding G0461 and G0462 except, as discussed below, as they pertain to errors identified with regard to the pricing of supplies.

Comment*:* Commenters alerted us to an error in the calculation of the supply price for SL483 and SL486. Commenters pointed out that the price for SL483 is $22.56/ml, rather than the .00256/ml that was listed in the database, and based on the unit of measure established in the direct PE inputs database for SL486, which costs $65.63 for 250 tests, the per test quantity should be 1, rather than 0.004.

Response*:* We agree with commenters that these prices were calculated incorrectly and have made the adjustments to the direct PE database.

c. Finalizing CY 2014 Interim Malpractice Crosswalks for CY 2015

In accordance with our malpractice methodology, we adjusted the malpractice RVUs for the CY 2014 new/revised/potentially misvalued codes for the difference in work RVUs (or, if greater, the clinical labor portion of the PE RVUs) between the source codes and the new/revised codes to reflect the specific risk-of-service for the new/revised codes. The interim final malpractice crosswalks were listed in Table 30 of the CY 2014 PFS final rule with comment period.

We received only one comment on our CY 2014 interim final cross walks. As detailed in the CY 2014 final rule with comment period, we assigned malpractice crosswalk of CPT code 31575 (Laryngoscopy, flexible fiberoptic; diagnostic) to CPT codes 43191-43195 and 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)) to CPT code 43196.

Comment: A commenter said that the established PLI crosswalk, CPT code 31575, for CPT code 43191-43196 is not appropriate because the latter services have a life-threatening risk

to patients and the same is not true for CPT code 31575. The commenter recommends instead that we utilize the RUC recommended crosswalk of bronchoscopy, rigid or flexible codes (CPT codes 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)) for CPT code 43191, 31625 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites) for CPT code 43192, 43193, and 43195, and 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)) for CPT codes 43194 and 43196.

Response: We continue to believe that our assigned CY 2014 malpractice crosswalks best define the malpractice risk associated with CPT codes 43191-43196. Therefore, we are finalizing our CY 2014 interim final crosswalks.

We received no comments on the CY 2014 interim final malpractice crosswalks and are finalizing them without modification for CY 2015.

The malpractice RVUs for these services are reflected in Addendum B of this CY 2014 PFS final rule with comment period. Since we are finalizing a five-year review of MP RVUs in this final rule with comment period, the MP RVUs assigned to this codes will also be affected by the updates due to this review. For details on the review, see section II.C.

d. Other New, Revised or Potentially Misvalued Codes with CY 2014 Interim Final RVUs Not Specifically Discussed in the CY 2015 Final Rule with Comment Period

For all other new, revised, or potentially misvalued codes with CY 2014 interim final RVUs that are not specifically discussed in this CY 2015 PFS final rule with comment period, we are finalizing for CY 2015, without modification, the CY 2014 interim final or CY 2014 proposed work RVUs, malpractice crosswalks, and direct PE inputs. Unless otherwise indicated,

we agreed with the time values recommended by the RUC or HCPAC for all codes addressed in this section. The time values for all codes are listed in a file called "CY 2014 PFS Work Time," available 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.

3. Establishing CY 2015 RVUs

a. Finalizing CY 2015 Proposed RVUs

In the CY 2015 proposed rule, we proposed CY 2015 work values for several codes. Table 24 contains a list of these codes and the final CY 2015 work RVUs. For more information on these codes and the establishment of the values, see section II.Bof this final rule with comment period.

TABLE 24: CY 2015 Final Work RVUS for Codes with Proposed Work RVUs

HCPCS Code	Long Descriptor	CY 2014 WRVU	Proposed CY 2015 Work RVU	CY 2015 Work RVU
G0389	Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening	0.58	0.58	0.58
G0416	Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method;	3.09	3.09	3.09
G0473	Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes	New	N/A	0.25
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	1.18	1.91	1.91
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)	1.17	1.54	1.54
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)	1.54	2.04	2.04
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)	1.50	1.87	1.87
77055	mammography; unilateral,	.70	.70	.70
77056	mammography; bilateral	.87	.87	.87
77057	screening mammography, bilateral (2-view film study of each breast)	.70	.70	.70
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.	New	.61	.61

b. Establishing CY 2015 Interim Final Work RVUs

Table 25 contains the CY 2015 interim final work RVUs for all codes for which we received RUC recommendations for CY 2015 and G-codes with interim final values for CY

2015. These values are subject to public comment. The column labeled "CMS Time Refinement" indicates whether CMS refined the time values recommended by the RUC or HCPAC.

This section discusses codes for which the interim final work RVU or time values assigned for CY 2015 vary from those recommended by the RUC or for which we do not have RUC recommendations.

TABLE 25: CY 2015 Interim Final Work RVUS for New/Revised or Potentially Misvalued Codes

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	1.48	1.10	1.10	No
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting	New	0.89	0.89	No
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	New	1.00	1.00	No
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting	New	1.10	1.10	No
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	New	7.13	7.13	No
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1-3 ribs	New	19.55	10.79	Yes
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 ribs	New	25.00	13.00	Yes
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs	New	35.00	17.61	Yes
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic	New	8.15	8.15	No
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral	New	8.05	7.58	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	New	4.00	4.00	No
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; thoracic	New	8.90	8.90	No
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	New	8.24	8.24	No
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)	New	4.00	4.00	No
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical	24.05	24.05	24.05	No
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure)	New	8.40	8.40	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	New	9.03	9.03	No
29200	Strapping; thorax	0.65	0.39	0.39	No
29240	Strapping; shoulder (eg, velpeau)	0.71	0.39	0.39	No
29260	Strapping; elbow or wrist	0.55	0.39	0.39	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
29280	Strapping; hand or finger	0.51	0.39	0.39	No
29520	Strapping; hip	0.54	0.39	0.39	No
29530	Strapping; knee	0.57	0.39	0.39	No
31620	Endobronchial ultrasound (ebus) during bronchoscopic diagnostic or therapeutic intervention(s) (list separately in addition to code for primary procedure[s])	1.40	1.50	1.40	No
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode	4.92	4.92	4.92	No
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator	5.87	5.87	5.87	No
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator	5.84	5.84	5.84	No
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator	6.07	6.07	6.07	No
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator	6.15	6.15	6.15	No
33223	Relocation of skin pocket for implantable defibrillator	6.55	6.55	6.55	No
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	9.04	No
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	8.33	No
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead	6.05	6.05	6.05	No
33241	Removal of implantable defibrillator pulse generator only	3.29	3.29	3.29	No
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy	23.57	23.57	23.57	No
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	13.99	13.99	13.99	No
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber	15.17	15.17	15.17	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system	6.06	6.06	6.06	No
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system	6.33	6.33	6.33	No
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	New	9.10	9.10	No
33271	Insertion of subcutaneous implantable defibrillator electrode	New	7.50	7.50	No
33272	Removal of subcutaneous implantable defibrillator electrode	New	5.42	5.42	No
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	New	6.50	6.50	No
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	New	32.25	32.25	No
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)	New	7.93	7.93	No
33946	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; initiation, veno-venous	New	6.00	6.00	No
33947	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; initiation, veno-arterial	New	6.63	6.63	No
33949	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; daily management, each day, veno-arterial	New	4.60	4.60	No
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)	New	8.15	8.15	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	New	8.43	8.15	No
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	New	9.83	9.11	No
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	New	9.43	9.11	No
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	New	16.00	16.00	No
33956	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older	New	16.00	16.00	No
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)	New	4.00	3.51	No
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)	New	4.05	3.51	No
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)	New	4.69	4.47	No
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)	New	4.73	4.47	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	New	9.00	9.00	No
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)	New	9.50	9.50	No
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	New	3.51	3.51	No
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	New	4.50	4.50	No
33969	Extracorporeal membrane oxygenation (ecmo)/extracorporeal life support (ecls) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	New	6.00	5.22	No
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	New	6.38	5.46	No
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	New	9.89	9.89	No
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	New	10.00	10.00	No
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)	New	4.04	4.04	No
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ecmo/ecls	New	15.00	15.00	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ecmo/ecls	New	9.50	9.50	No
34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time	New	C	B	N/A
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	C	N/A
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	C	N/A
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	C	N/A
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	C	N/A

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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	C	N/A
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	C	N/A
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	C	N/A
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	C	N/A
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated	6.72	5.30	5.30	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	3.38	2.65	2.65	No
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated	6.72	5.30	5.30	No
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)	3.38	2.65	2.65	No
36818	Arteriovenous anastomosis, open; by upper arm cephalic vein transposition	11.89	13.00	12.39	No
36819	Arteriovenous anastomosis, open; by upper arm basilic vein transposition	13.29	15.00	13.29	No
36820	Arteriovenous anastomosis, open; by forearm vein transposition	14.47	13.99	13.07	No
36821	Arteriovenous anastomosis, open; direct, any site (eg, cimino type) (separate procedure)	12.11	11.90	11.90	No
36825	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft	14.17	15.93	14.17	No
36830	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (eg, biological collagen, thermoplastic graft)	12.03	11.90	12.03	No
36831	Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure)	8.04	11.00	11.00	Yes
36832	Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	10.53	13.50	13.50	Yes
36833	Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	11.98	14.50	14.50	Yes

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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	New	15.00	15.00	No
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	New	9.03	9.03	No
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	New	1.48	I	N/A
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	New	3.11	I	N/A
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)	New	4.44	I	N/A
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed)	New	4.96	I	N/A
44403	Colonoscopy through stoma; with endoscopic mucosal resection	New	5.81	I	N/A
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance	New	3.13	I	N/A
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	New	3.33	I	N/A
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures	New	4.41	I	N/A
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	New	5.06	I	N/A
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	New	4.24	I	N/A

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	New	2.97	I	N/A
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	New	2.98	I	N/A
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	New	3.83	I	N/A
45350	Sigmoidoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	New	1.78	I	N/A
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)	New	4.98	I	N/A
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed)	New	5.50	I	N/A
45390	Colonoscopy, flexible; with endoscopic mucosal resection	New	6.35	I	N/A
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	New	4.78	I	N/A
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	New	4.30		N/A
45399	Unlisted procedure, colon	New	None	I	N/A
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	New	1.60	I	N/A
46607	Anoscopy; with high-resolution magnification (hra) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple	New	2.20	I	N/A
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	New	9.13	9.13	No
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	New	4.50	4.50	No
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure)	New	1.20	1.20	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
55840	Prostatectomy, retropubic radical, with or without nerve sparing;	24.63	21.36	21.36	No
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	26.49	24.16	21.36	No
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	30.67	29.07	25.18	No
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;	14.70	12.29	12.29	No
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	16.56	14.16	14.16	No
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	16.87	14.39	14.39	No
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	18.37	15.60	15.60	No
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;	15.88	13.36	13.36	No
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	17.69	15.00	15.00	No
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;	20.09	17.71	17.71	No
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	23.11	20.79	20.79	No
62284	Injection procedure for myelography and/or computed tomography, lumbar (other than c1-c2 and posterior fossa)	1.54	1.54	1.54	No
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical	New	2.29	2.29	No
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic	New	2.29	2.29	No
62304	Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral	New	2.25	2.25	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
62305	Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)	New	2.35	2.35	No
64486	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)	New	1.27	1.27	No
64487	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)	New	1.48	1.48	No
64488	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	New	1.60	1.60	No
64489	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	New	1.80	1.80	No
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	7.15	5.44	5.44	No
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft	New	14.00	14.00	No
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft	16.30	15.00	15.00	No
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft	New	9.58	9.58	No
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft	9.58	10.58	10.58	No
67036	Vitrectomy, mechanical, pars plana approach;	13.32	12.13	12.13	No
67039	Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation	16.74	13.20	13.20	No
67040	Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation	19.61	14.50	14.50	No
67041	Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (eg, macular pucker)	19.25	16.33	16.33	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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)	22.38	16.33	16.33	No
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	23.24	17.40	17.40	No
67255	Scleral reinforcement (separate procedure); with graft	10.17	10.17	8.38	No
70486	Computed tomography, maxillofacial area; without contrast material	1.14	0.85	0.85	No
70487	Computed tomography, maxillofacial area; with contrast material(s)	1.30	1.17	1.13	No
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections	1.42	1.30	1.27	No
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.75	1.75	1.75	No
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.92	1.82	1.82	No
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.81	1.81	1.81	No
72240	Myelography, cervical, radiological supervision and interpretation	0.91	0.91	0.91	No
72255	Myelography, thoracic, radiological supervision and interpretation	0.91	0.91	0.91	No
72265	Myelography, lumbosacral, radiological supervision and interpretation	0.83	0.83	0.83	No
72270	Myelography, 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation	1.33	1.33	1.33	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	2.20	2.20	2.20	No
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.90	1.82	1.82	No
74230	Swallowing function, with cineradiography/videoradiography	0.53	0.53	0.53	No
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete	New	0.73	0.73	No
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited	New	0.68	0.68	No
76700	Ultrasound, abdominal, real time with image documentation; complete	0.81	0.81	0.81	No
76705	Ultrasound, abdominal, real time with image documentation; limited (eg, single organ, quadrant, follow-up)	0.59	0.59	0.59	No
76770	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; complete	0.74	0.74	0.74	No
76775	Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; limited	0.58	0.58	0.58	No
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete	0.69	0.69	0.69	No
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (eg, for follicles)	0.38	0.50	0.50	No
76930	Ultrasonic guidance for pericardiocentesis, imaging supervision and interpretation	0.67	0.67	0.67	No
76932	Ultrasonic guidance for endomyocardial biopsy, imaging supervision and interpretation	C	0.85	0.85	No
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation	0.67	0.67	0.67	No
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation	0.38	0.92	0.92	No
77061	Digital breast tomosynthesis; unilateral	New	0.70	I	N/A
77062	Digital breast tomosynthesis; bilateral	New	0.90	I	N/A
77063	Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure)	New	0.60	0.60	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)	0.20	0.20	0.20	No
77085	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment	New	0.30	0.30	No
77086	Vertebral fracture assessment via dual-energy x-ray absorptiometry (dxa)	New	0.17	0.17	No
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	0.62	No
77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)	New	1.40	1.40	No
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)	New	2.90	2.90	No
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)	New	1.50	1.40	No
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)	New	1.83	1.83	No
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)	New	2.90	2.90	No
77385	Intensity modulated radiation treatment delivery (imrt), includes guidance and tracking, when performed; simple	New		I	N/A
77386	Intensity modulated radiation treatment delivery (imrt), includes guidance and tracking, when performed; complex	New		I	N/A
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed	New	0.58	I	N/A

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
77402	Radiation treatment delivery, >1 mev; simple	0.00		I	N/A
77407	Radiation treatment delivery, >1 mev; intermediate	0.00		I	N/A
77412	Radiation treatment delivery, >1 mev; complex	0.00		I	N/A
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)	New	0.65	0.42	No
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	I	0.70	0.70	No
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure	New	0.77	0.77	No
88356	Morphometric analysis; nerve	3.02	2.80	2.80	No
88364	In situ hybridization (eg, fish), per specimen; each additional single probe stain procedure (list separately in addition to code for primary procedure)	New	0.88	0.53	No
88365	In situ hybridization (eg, fish), per specimen; initial single probe stain procedure	1.20	0.88	0.88	No
88366	In situ hybridization (eg, fish), per specimen; each multiplex probe stain procedure	New	1.24	1.24	No
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure	1.30	0.86	0.73	No
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure	1.40	0.88	0.88	No
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)	New	0.88	0.53	No
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)	New	0.86	0.43	No
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure	New	1.04	0.93	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure	New	1.40	1.40	No
88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	1.56	1.14	1.14	No
88381	Microdissection (ie, sample preparation of microscopically identified target); manual	1.18	0.53	0.53	No
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report	New	0.30	0.30	No
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	New	0.17	0.17	No
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	1.50	No
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording	0.40	0.40	0.40	No
92542	Positional nystagmus test, minimum of 4 positions, with recording	0.33	0.48	0.48	No
92543	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests), with recording	0.10	0.35	0.10	No
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording	0.26	0.27	0.27	No
92545	Oscillating tracking test, with recording	0.23	0.27	0.27	No
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	New	0.85	0.85	No
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	New	0.74	0.74	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system	0.85	0.85	0.85	No
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system	1.15	1.15	1.15	No
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system	1.25	1.25	1.25	No
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system	0.45	0.45	0.45	No
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	0.92	No
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	2.20	3.18	2.55	No
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only	0.95	1.00	0.51	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
93314	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only	1.25	2.80	2.10	Yes
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	C	3.29	2.94	No
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only	0.95	1.50	0.85	No
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only	C	3.00	2.09	Yes
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	C	2.40	2.40	No
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	0.38	No
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	0.15	No
93325	Doppler echocardiography color flow velocity mapping (list separately in addition to codes for echocardiography)	0.07	0.07	0.07	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
93355	Echocardiography, transesophageal (tee) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,tavr, transcathether 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	New	4.66	4.66	No
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)	New	3.65	3.29	No
93880	Duplex scan of extracranial arteries; complete bilateral study	0.60	0.80	0.80	No
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.40	0.50	0.50	No
93886	Transcranial doppler study of the intracranial arteries; complete study	0.94	1.00	0.91	No
93888	Transcranial doppler study of the intracranial arteries; limited study	0.62	0.70	0.50	No
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	New	0.55	N	No
93925	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study	0.80	0.80	0.80	No
93926	Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study	0.50	0.60	0.50	No
93930	Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study	0.46	0.80	0.80	No
93931	Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study	0.31	0.50	0.50	No
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study	0.70	0.70	0.70	No
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study	0.45	0.45	0.45	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
93975	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study	1.80	1.30	1.16	No
93976	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study	1.21	1.00	0.80	No
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study	0.65	0.97	0.80	No
93979	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study	0.44	0.70	0.50	No
93990	Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)	0.25	0.60	0.50	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
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	1.50	0.90	0.80	No
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)	0.92	NA	0.49	No

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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	0.55	No
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	0.60	No
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	New	0.41	C	
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 ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	New	0.46	C	Yes
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	C	0.35	0.35	No
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session	2.34	2.11	2.11	No
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	New	4.50	4.50	No
99188	Application of topical fluoride varnish by a physician or other qualified health care professional	New	0.20	N	N/A

HCPCS Code	Long Descriptor	CY 2014 WRVU	RUC/HCPAC Recommended Work RVU	CY 2015 Work RVU	CMS Time Refinement
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.;	1.00	1.00	B	N/A
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	New	1.50	I	N/A
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)	New	1.40	I	N/A
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206)	New	N/A	0.60	N/A

i. Code Specific Issues

(1) Internal 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 (flail chest)) and replaced it with three CPT codes 21811, 21812 and 21813, to report internal fixation of rib fracture. The RUC recommended valuing these three codes as 90-day global services. For the reasons we articulate in section II.B.4 of this final rule with comment period about the difficulties in accurately valuing codes as 90-day global services, we believe that the valuation of these codes should be as 0-day global services. In addition, we

believe this is particularly appropriate for these codes because the number of RUC-recommended inpatient and outpatient visits included in the postservice time seems higher than would likely occur. The vignette for CPT code 21811 describes an elderly patient who falls and experiences three rib fractures that require internal fixation. The seven visits included in the postservice time for this code seem high since the vignette does not describe a very ill patient. The vignettes for CPT codes 21812 and 21813 describe patients experiencing significant rib fractures in car accidents that require internal fixation. We believe that in these scenarios, injuries beyond rib fractures are likely, and as a result, we believe it is likely that multiple practitioners would be involved in providing post-operative care. If other practitioners would furnish care in the post-surgery period, we believe the ten and thirteen postservice visits included in CPT codes 21812 and 21813 would likely not occur. By valuing these codes as 0-day globals, we do not need to address these issues because the surgeon will be able to bill separately for the postoperative services that are furnished after the day of the procedure.

To value these services as 0-day global codes, we subtracted the work RVUs related to the postoperative services from the total work RVU. We are establishing CY 2015 interim work RVUs of 10.79 for CPT code 21811, of 13.00 for CPT code 21812, and of 17.61 for CPT code 21813. We also refined the RUC recommended time by subtracting the time associated with the postoperative visits. By removing the work and time associated with visits in the postoperative period, the remaining work and time reflect the work and time of services furnished on the day of surgery.

(2) Percutaneous Vertebroplasty and Augmentation (CPT Codes 22510, 22511, 22512, 22513, 22514 and 22515)

For CY 2015, the CPT Editorial Panel replaced the eight existing percutaneous vertebroplasty with six new codes, CPT codes 22510-22515, which include the percutaneous

vertebroplasty and the image guidance together. We are establishing the RUC-recommended work values as interim final for CY 2015 for all of the codes in this family except CPT code 22511.

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 value for CPT code 22511 by crosswalking this 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 physician in the two services differs, we do not agree that this crosswalk is appropriate. Instead, we believe a more appropriate analogy is found in the difference between the work values for the predecessor codes for CPT codes 22510 and 22511, CPT codes 22520 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic) and 22521 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic; lumbar). Accordingly, we are applying the difference in the current work RVUs for CPT codes 22520 and 22521 to the work RVU that we are establishing for CPT code 22510. We believe this increment establishes the appropriate rank order in this family and thus are assigning an interim final work RVU of 7.58 for CPT code 22511, which is 0.57 work RVUs lower than the CY 2015 work RVU for CPT code 22510.

(3) Endobronchial Ultrasound (EBUS) (CPT Code 31620)

For CY 2015, the RUC reviewed CPT code 31620 because it was identified through the High Volume Growth Services, which are those services for which Medicare utilization increased by at least 100 percent from 2006 to 2011. CPT code 31620 is an add-on code to CPT code 31629 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)).

Medicare data show that 82 percent of the time when EBUS is billed it is billed with CPT code 31629. Given this relationship, we believe that CPT code 31620 should be bundled with CPT code 31629. The specialty societies maintain that EBUS is distinct from bronchoscopy with biopsy because the intraservice work of EBUS occurs between the two components of the base code, bronchoscopy and biopsy. However, based upon the discussion at the RUC meeting, we believe that the biopsy actually occurs during the EBUS and the biopsy is actually performed through the EBUS scope. Thus, we do not believe the EBUS code descriptor accurately describes the service nor is it possible to accurately value this service when the descriptor is inaccurate. Therefore, for CY 2015 we are maintaining the CY 2014 work RVU for CPT code 31620. We understand that the RUC will review this code for CY 2016.

(4) Extracorporeal Membrane Oxygenation (ECMO)/Extracorporeal Life Support (ECLS) (CPT Codes 33946, 33947, 33948, 33949, 33951- 33959, 33962-33966, 33969, 33984 -33989)

In the CY 2014 PFS final rule with comment period, CPT codes 33960 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial day) and 33961 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; each subsequent day) were identified as potentially misvalued codes. Specifically, the services were originally valued when they were primarily provided to premature neonates; but the services are now typically used in treating adults with severe influenza, pneumonia, and respiratory distress syndrome. For CY 2015, CPT codes 33960 and 33961 were deleted and replaced with 25 new codes to describe this treatment. We are assigning the RUC-recommended work values as interim final for CY 2015 for all of the codes in this family except CPT codes 33952, 33953, 33954, 33957, 33958 and 33959, 33962, 33969, and 33984.

We accepted the RUC-recommended work RVU of 8.15 for CPT code 33951, which describes an ECMO peripheral cannula(e) insertion for individuals up to 5 years of age. The

RUC recommended a work RVU of 8.43 for CPT code 33952, which describes the same procedure for individuals 6 years and older. We do not believe this difference in the age of the patient increases the work of the service from the younger patient. The fact that the RUC-recommended intraservice time is identical for both codes supports our view that the work RVU should be the same for both codes. Therefore, for CY 2015, we are establishing an interim final work RVUs of 8.15 for CPT code 33952, the same as we established for CPT 33951 based upon the RUC-recommendation for the younger patient.

The RUC recommended work RVUs of 9.83 and 9.43 for CPT codes 33953 and 33954, respectively. For the same reasons discussed above, we are establishing the same work values for the code for treatment of patients from birth through 5 years of age and the code for treatment of patients 6 years and older. To determine the value for these codes, we adjusted the work RVU of the equivalent percutaneous codes, CPT code 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)) and CPT code 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)), to reflect the greater work of the open procedure codes, CPT codes 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) and 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). To measure the difference in work between these two sets of codes we applied the 0.96 RVU differential

between the percutaneous arterial CPT code 33620 (Application of right and left pulmonary artery bands (for example, hybrid approach stage 1)) and the open arterial CPT code 36625 (Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); cutdown) codes. This measure allows us to establish the difference in work between the sets of codes based upon the difference in intensity. Accordingly, we are assigning an interim final work RVU to CPT codes 33953 and 33954 of 9.11.

Unlike other codes in this family for which the RUC-recommended work value was based upon the 25th percentile of the survey, for CPT codes 33957 and 33958 the RUC recommended a work RVU of 4.00 and 4.05, respectively, based upon the survey median. We believe that, like other services in this family, these codes should be valued based upon the 25th percentile values of the survey because those values best describe the work involved in these procedures and results in the appropriate relativity amongst the codes in the family. Therefore, for CY 2015 we are assigning an interim final work RVU of 3.51 for CPT codes 33957 and 33958.

We believe the RUC-recommended work RVUs of 4.69 and 4.73 for CPT codes 33959 and 33962 respectively, overstate the work involved in the services. As we discussed above for CPT codes 33953 and 33954, we believe the differential between the percutaneous arterial and open arterial CPT codes more appropriately reflects the work involved in these services. Accordingly we are establishing a CY 2015 interim final work RVU of 4.47 for CPT codes 33959 and 33962.

After researching comparable codes, we believe the RUC-recommended work RVUs of 6.00 and 6.38 for CPT codes 33969 and 33984, respectively, overstates the work involved in the procedures. For the same reasons and following the same valuation methodology utilized above, we added the differential between the percutaneous arterial and arterial cutdown codes, 0.96

RVU, to the CY 2015 interim final work RVU of 4.50 for CPT code 33966, which is the percutaneous counterpart of CPT code 33984. This results in a work RVU of 5.46 for CPT code 33984. Because CPT code 33969 has 2 minutes less intraservice time than CPT code 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), we adjusted the work RVU of CPT code 33984 for the decrease in time to get a work RVU of 5.22 for CPT code 33969 (Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age). Therefore, for CY 2015 we are establishing an interim final work RVU of 5.46 to CPT code 33984 and 5.22 to CPT code 33969.

(5) Fenestrated Endovascular Repair (FEVAR) Endograft Planning (CPT Code 34839)

For CY 2015, CPT code 34839 was created to report the planning that occurs prior to the work included in the global period for a FEVAR. The RUC recommended that we contractor price this service as the RUC survey response rate was too low to provide the basis for an appropriate valuation. In general, we prefer that planning be bundled with the underlying service, and we have no reason to believe bundling is not appropriate in this case. Accordingly, we are assigning a PFS procedure status indicator of B (Bundled Code) to CPT code 34839.

(6) AV Anastomosis (CPT Codes 36818, 36819, 36820, 36821, 36825, 36830, 36831, 36832, and 36833)

In the CY 2013 PFS final rule with comment period, the AV anastomosis family of services were determined to be potentially misvalued due to rank order anomalies, including CPT codes 36818-36821 and CPT codes 36825-36830. The RUC recommendations that we received in response also included CPT codes 36831-36833. We are assigning the RUC-recommended work RVUs as CY 2015 interim final values for CPT codes 36821, 36831, 36832

and 36833. For CPT code 36831, 36832, and 36833, we are refining to remove the additional 10 minutes of preservice evaluation time. The RUC added 10 minutes of additional pre-service time to these codes for determining the best source of access,. These three codes are revision/repair codes and as such do not need the additional time to determine the access source. For CPT code 36818, the RUC recommended an approximately 12 percent increase in work RVU but a total time increase of approximately 4.2 percent. We are assigning a CY 2015 interim final work RVU of 12.39, which reflects a 4.2 percent increase from the current value based upon the increase in total time.

For CPT code 36819, the RUC-recommended intraservice and total times are only minimally different than the current times. Even though the intraservice and total times decreased minimally, the RUC increased the work RVU. We believe that the small decrease in total time, 2 percent, suggest that the current work RUV is appropriate. Therefore, we are assigning a CY 2015 interim final work RVU of 13.29, which is the current work value.

The RUC recommended a work value of 13.99 for CPT code 36820. The RUC recommended that the postservice time of CPT code 36820 be reduced by removing visits. Specifically, a CPT code 99231 and one-half of a CPT code 99238 were removed from the service, which would equal 1.40 RVU. We do not believe that this reduction was accounted for in the RUC-recommended work RVU. To account for this reduction in visits, we are establishing a CY 2015 interim final work RVU of 13.07 for CPT 36820 which reflects a 1.40 work RVU reduction in the current work RVU.

For CPT code 36825, the RUC-recommended intraservice and total times are only minimally different than the current times. However, the RUC increased the work RVU. We do not believe the work RVU should be increased without corresponding time changes. Therefore, we believe the appropriate CY 2015 interim final work RVU is the current work value of 14.17.

For CPT code 36830, the RUC-recommended intraservice and total times are only minimally different than the current times. However, the RUC decreased the work RVU. We do not believe the work RVU should be decreased without corresponding time changes. Therefore, we are establishing a CY 2015 interim final work RVU of 12.03, which is equal to the current work RVU.

Furthermore, we refined the total time values as follows: 238 minutes for CPT code 36831, 266 minutes for CPT code 36832, and 296 minutes for CPT code 36833.

(7) Illeoscopy, Pouchoscopy, Colonoscopy through Stoma, Flexible Sigmoidoscopy and Colonoscopy (CPT Codes 44380, 44381, 44382, 44383, 44384, 44385, 44386, 44388, 44389, 44390, 44391, 44392, 44393, 44394, 44397, 44401, 44402, 44403, 44404, 44405, 44406, 44407, 44408, 44799, 45330, 45331, 45332, 45333, 45334, 45335, 45337, 45338, 45346, 45340, 45341, 45342, 45345, 45347, 45349, 45350, 45378, 45379, 45380, 45381, 45382, 45383, 45388, 45384, 45385, 45386, 45387, 45389, 45390, 45391, 45392, 45393, 45398, 45399, 0226T, 46601, 0227T, and 46607 and HCPCS Codes G6018, G6019, G6020, G6021, G6022, G6023, G6024, G6025, G6027, G6028)

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 the current practice. The RUC subsequently provided recommendations to CMS for valuing these services. In comments on the proposed rule, stakeholders noted our proposal to begin including proposed values for new, revised and potentially misvalued codes in the proposed rule. Commenters suggested that, rather than implementing this new process in CY 2016, we should implement it immediately and thus defer the valuation of the new GI code set until CY 2016. They indicated that the opportunity to comment prior to implementation of the new values was

important for these codes, many of which have high utilization. In addition, in this final rule with comment period we discuss the need to modify how moderate sedation is reported and valued. Since the valuation of most codes in this code set includes moderate sedation, stakeholders suggested that we revalue these codes in conjunction with any changes in reporting and valuation of moderate sedation.

We agree with the commenters. In light of the substantial nature of this code revision and its relationship to the policies on moderate sedation, we are delaying revaluation of these codes until CY 2016 when we will be able to include proposals in the proposed rule for their valuation, along with consideration of policies for moderate sedation. Accordingly for CY 2015, we are maintaining the inputs for the lower gastrointestinal endoscopy codes at the CY 2014 levels. (Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.) Since the code set is changing for CY 2015, including the deletion of some of the CY 2014 codes, we are creating G-codes as necessary to allow practitioners to report services to CMS in the same way in CY 2015 that they did in CY 2014 and to maintain payment under the PFS based on the same inputs. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes for lower gastrointestinal endoscopy that will not be recognized by Medicare for CY 2015 are denoted with an "I" (Not valid for Medicare purposes) in Table 26. The chart below lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.

TABLE 26: Lower Gastrointestinal Endoscopy G-Codes Replacing CY 2015 CPT Codes

CY 2014 CPT Code[1]	CY 2015 HCPCS Code	Long Descriptor
44383	G6018	Ileoscopy,through stoma;with transendoscopic stent placement (includes predilation)
44393	G6019	Colonoscopy through stoma;with ablation of tumor(s),polp(s),or other lesion(s)not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
44397	G6020	Colonoscopy through stoma;with transendoscopic stent placement (includes predilation)
44799	G6021	Unlisted procedure,intestine
45339	G6022	Sigmoidoscopy, flexible; with ablation of tumor(s),polyp(s),or other lesions(s)not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
45345	G6023	Sigmoidoscopy, flexible; with transenoscopic stent placement (includes predilation)
45383	G6024	Colonoscopy, flexible, proximal to splenic flexure; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
45387	G6025	Colonoscopy, flexible, proximal to splenic flexure; with transendoscopic stent placement (includes predilation)
0226T	G6027	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed
0227T	G6028	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)

(8) Prostatectomy (CPT Codes 55842 and 55845)

In the CY 2014 PFS final rule with comment period, we finalized CPT codes 55842 and 55845 as potentially misvalued codes. For CY 2015, the RUC provided recommendations for these services of 29.07 and 24.16, respectively. We disagreed with the RUC-recommended crosswalk for CPT code 55842. To value CPT code 55842, we are crosswalking it to CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing) due to their identical times. Therefore, we are establishing an interim final work RVU of 21.36.

For CPT code 55845, we are establishing a work RVU of 25.18 based upon the 25th percentile of the survey. This work RVU results in an 18 percent decrease from the current work RVU, which we believe reflects the changes since the last valuation, based upon a 20 percent decrease in intraservice time and the 29 percent decrease in total time.

[1] This chart only contains CY 2014 codes for which a HCPCS code is being used for CY 2015. Addendum B contains a complete list of CPT and HCPCS codes being recognized by Medicare under the PFS for CY 20115.

(9) Aqueous Shunt (CPT Code 66179, 66180, 66184, 66185, and 67255)

After identifying CPT code 66180 through the Harvard-Valued Annual Allowed Charges Greater than $10 million screen, the RUC recommended work RVUs for the aqueous shunt family for CY 2015. We are establishing the RUC-recommended work RVUs as interim final for all codes in this family except CPT code 67255. The RUC recommended maintaining the CY 2014 work RVU of 10.17 for CPT 67255. However, we believe maintaining this value would be inconsistent with the RUC-recommended decreases in total time for the service. As a result, we reduced the work RVU by the same percentage that the RUC recommended a reduction in total time, which results in a CY 2015 interim final work RVU of 8.38 for CPT code 67255.

(10) Computed Tomography (CT) – Maxillofacial (CPT Codes 70486, 70487 and 70488)

The RUC's Relativity Assessment Workgroup identified CPT code 70486 for review through the CMS/Other Source – Utilization over 250,000 screen. The involved specialty societies expanded the survey to include CPT codes 70487 and 70488, all of which involve maxillofacial CTs. We are establishing the RUC-recommended work RVU of 0.85 as the CY 2015 interim final value for CPT code 70486, which is without contrast material. The RUC established this recommendation by crosswalking this code to the equivalent code in the CT for the head or brain, CPT code 70450 (Computed tomography, head or brain without contrast). We agree with that method and in order to maintain rank order within and across CT families, we crosswalked CPT code 70487, which is with contrast material(s), to the CPT code 70460, which is the equivalent code in the head or brain family and CPT code 70488, which is without contrast materials followed by contrast material(s) and further sections to CPT code 70470, which is the equivalent code in the head or brain family. Therefore, for CY 2015 we are establishing interim final work RVUs of 1.13 for CPT code 70487 and 1.27 for CPT code 70488.

(11) 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). The difference between the new codes is that one is for complete breast ultrasound procedures and the other is for limited. We are assigning the RUC-recommended work RVUs of 0.73 and 0.68 to CPT codes 76641 and 76642, respectively, as interim final. One difference between the predecessor code and the new ones is that while the predecessor code was used to report unilateral or bilateral breast ultrasounds, the new codes are unilateral ones. To appropriately adjust payment when bilateral procedures are furnished under the PFS, payments are adjusted to 150 percent of the unilateral payment when a service has a bilateral payment indicator assigned. We are assigning a bilateral payment indicator to these codes.

(12) Radiation Therapy Codes (CPT Codes 76950, 77014, 77421, 77387, 77401, 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, 77416, 77418, 77385, 77386, 0073T, and 0197T and HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

CPT revised the radiation therapy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that the provision of radiation therapy could not be accurately reported under the existing code set. The RUC subsequently provided recommendations to CMS for valuing these services. Some stakeholders approached CMS with concerns about these codes being revalued as interim final in the final rule with comment period, noting that these codes account for the vast majority of

Medicare payment for radiation therapy centers. They noted our proposal to begin including proposals to value new, revised and potentially misvalued codes in the proposed rule, and suggested that these code valuations should be delayed to CY 2016 so that they could be addressed under this new process. This would provide affected stakeholders the opportunity to comment prior to the valuations being effective. They also noted that since they do not participate in the RUC, they did not have the opportunity to provide input to the recommendations nor will they have information about the RUC recommendations until CMS makes this information available in the final rule with comment period.

In response to comments and in light of the substantial nature of this code revision, we are delaying revaluation of these codes until CY 2016. The coding changes for CY 2015 involve significant changes in how radiation therapy services and associated image guidance are reported. There is substantial work to be done to assure the new valuations for these codes accurately reflect the coding changes. Accordingly we are delaying the use of the revised radiation therapy code set until CY 2016 when we will be able to include proposals in the proposed rule for their valuation. We are maintaining the inputs for radiation therapy codes at the CY 2014 levels. (Note: Due to budget neutrality adjustments and other system-wide changes, the payment rates may change.) Since the code set has changed and some of the CY 2014 codes are being deleted, we are creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes. The new and revised CY 2015 CPT codes that will not be recognized by Medicare for CY 2015 are denoted with an “I” (Not valid for Medicare purposes) on Table 27. The chart below lists the G-codes that we are creating and the CY 2014 CPT codes that they are replacing.

Additionally, we would like to note that changes to the prefatory text modify the services that are appropriately billed with CPT code 77401, which is used to report superficial radiation therapy. This change effectively means that CPT code 77401 is now bundled with many other procedures supporting superficial radiation therapy. However, the RUC did not review superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. Stakeholders have suggested to us that the change to the prefatory text prohibits them from billing for codes that were previously frequently billed in addition to this code and as a result there will be a significant reduction in their payments." We are interested in information on whether the new code set combined with modifications in prefatory text allows for appropriate reporting of the services associated with superficial radiation and whether the payment continues to reflect the relative resources required to furnish superficial radiation therapy services.

TABLE 27: Radiation Therapy G-Codes Replacing CY 2015 CPT Codes

CY 2014 CPT Code[2]	CY 2015 HCPCS Code	Long Descriptor
76950	G6001	Ultrasonic guidance for placement of radiation therapy fields
77421	G6002	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77402	G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5MeV
77403	G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10MeV
77404	G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19MeV
77406	G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 MeV or greater
77407	G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; up to 5MeV
77408	G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 6-10MeV
77409	G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 11-19MeV
77411	G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks; 20 MeV or greater
77412	G6011	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5MeV
77413	G6012	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10MeV
77414	G6013	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19MeV
77416	G6014	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20MeV or greater
77418	G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
0073T	G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
0197T	G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy(eg,3D positional tracking, gating, 3D surface tracking), each fraction of treatment

(13) Breast Tomosynthesis (CPT codes 77061, 77062, and 77063)

For CY 2015, the CPT Editorial Panel created three codes to describe digital breast tomosynthesis services: 77061 (Digital breast tomosynthesis; unilateral), 77062 (Digital breast

[2] This chart only contains CY 2014 codes for which a HCPCS code is being used for CY 2015. Addendum B contains a complete list of CPT and HCPCS codes being recognized by Medicare under the PFS for CY 2015.

tomosynthesis; bilateral) and 77063 (Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) and we received RUC recommendations for these codes. Currently, these services are reported to Medicare using G0202, G0204, and G0206, which describe the equivalent procedures using any digital technology (2-D or 3-D). In addition, film mammography is reported to Medicare using CPT codes 77055, 77056 and 77057).

In the proposed rule, based upon our belief that digital mammography is now typical, we proposed to replace the G-codes that currently describe all digital mammography services under Medicare with the CPT codes, to value the CPT codes for CY 2015 based upon the current G-code values, and to include the CPT codes on the potentially misvalued code list since the resources involved in furnishing these services had not been evaluated in more than a decade. Having reassessed the proposal in light of the new codes and RUC recommendations for tomosynthesis and the comments received upon our proposal, we are finalizing a modified proposal. For a discussion of our proposal, a summary of the comments we received, and our policy for CY 2015, see section II.B.4.

With regard to screening mammography, the CPT coding system now has an add-on CPT code for tomosynthesis. This coding scheme is consistent with the FDA requiring a 2-D mammography when tomosynthesis is used for screening purposes. Accordingly, we will recognize CPT code 77063 to be reported, when tomosynthesis is used in addition to 2-D mammography. Since CPT code 77063 is an add-on code, and does not have an equivalent CY 2014 code, we believe it is appropriate to value it on an interim final basis in advance of receiving the RUC recommendations for other mammography services. We are assigning it a CY 2015 interim final work RVU of 0.60 as recommended by the RUC.

Whenever feasible, it is our strong preference to value entire families together in order to avoid rank order anomalies. In this final rule with comment period, we are including the codes for digital mammography on the potentially misvalued code list, which currently include tomosynthesis as well as 2-D mammography. Accordingly, we will wait to value the new diagnostic mammography tomosynthesis codes until we have received recommendations from the RUC for all mammography services, In the interim, we are assigning a PFS indicator of "I" to 77061 and 77062. Those furnishing diagnostic mammography using tomosynthesis will continue to report G0204 and G0206 as appropriate. In addition, we are creating a new code, G-2079 (Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to G0204 or G0206)) as an add-on code that should be reported in addition to the relevant 2-D diagnostic mammography G-code to recognize the additional resources involved in furnishing diagnostic breast tomosynthesis. We will assign it the same inputs as CPT code 77063 because we believe it describes a similar service.

(14) Isodose Calculation with Isodose Planning Bundle (CPT Code 77316)

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 are establishing the RUC-recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316. We disagree with the RUC-recommended crosswalk for this service because we do not believe it is an appropriate match in work. The RUC crosswalked CPT code 77318 to CPT code 77307, both of which are complex isodose planning codes in the same family. We believe that the RUC should have crosswalked CPT code 77316, a simple isodose planning code, to the corresponding simple isodose planning code in the same family, CPT code 77306. Therefore, for CY 2015 we are establishing an interim final work RVU of 1.40 for CPT code 77316.

(15) Immunohistochemistry (CPT codes 88341, 88342, and 88344; HCPCS codes G0461 and G0462)

In the CY 2014 PFS final rule with comment period (78 FR 74341), we assigned a status indicator of I (Not valid for Medicare purposes) to CPT codes 88341, 88342, and 88343 and instead created two G-codes, G0461 and G0462, to report immunohistochemistry services. We did this in part to avoid creating incentives for overutilization. For CY 2015, the CPT coding was revised with the creation of two new CPT codes, 88341 and 88344, the revision of CPT code 88342 and the deletion of CPT code 88343. We believe that the revised coding structure addresses the concerns that we had with the CY 2014 coding regarding the creation of incentives and overutilization. Accordingly, we are deleting the G-codes and assigning interim final values for these CPT code codes for CY 2015. We are establishing the RUC-recommended work RVUs as interim final for CY 2015 for CPT codes 88342 and 88344.

In the past for similar procedures in this family, the RUC recommended a work RVU for the add-on code that was 60 percent of the base code. For example, the RUC-recommended work RVU for CPT code 88334 (Pathology consultation during surgery; cytologic examination (for example, touch prep, squash prep), each additional site (List separately in addition to code for primary procedure)) is 60 percent of the work RVU of the base CPT code 88333 (Pathology consultation during surgery; cytologic examination (for example, touch prep, squash prep), initial site). Similarly, the RUC-recommended work RVU for CPT code 88177 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)) is 60 percent of the recommended value for the base CPT code 88172 (Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site). We believe that the

relative resources involved in furnishing an add-on service in this family would be reflected appropriately using the same 60 percent metric. To value CPT code 88341, we calculated 60 percent of the work RVU of the base CPT code 88342, which has a work RVU of 0.70; resulting in a work RVU of 0.42 for CPT code 88341.

(16) Morphometric Analysis In Situ Hybridization for Gene Rearrangement(s) (CPT Codes 88364, 88365, 88366, 88368, 88369, 88373, and 88374 and 88377)

For CY 2014, the in situ hybridization procedures, CPT codes 88365, 88367 and 88368, were revised to specify "each separately identifiable probe per block;" three new add-on codes (CPT codes 88364, 88373, 88369) were created to specify "each additional separately identifiable probe per slide;" and three new codes were created to specify "each multiplex probe stain procedure." We are establishing the RUC-recommended work RVUs as interim final for CY 2015 for CPT codes 88365, 88366, 88368, and 88377.

CPT code 88367 is the computer assisted version of morphometric analysis, analogous to 88368 which is the manual version. We have accepted the RUC recommended work RVU of 0.88 for 88368 which has 30 minutes of intraservice time. CPT code 88367 only has 25 minutes of intraservice time and we do not believe that the RUC recommended work RVU of 0.86 adequately reflects that change in time. We believe that the ratio of the intraservice times (25/30) applied to the work RVU (0.88) adequately reflects the difference in work. Therefore, we are assigning an interim final work RVU to CPT code 88367 of 0.73.

Similarly, CPT code 88374 is the computer assisted version of CPT code 88377 but with a drop in intraservice time from 45 minutes to 30 minutes. We believe applying this ratio to the work RUV of 88377 more accurately reflects the work. Therefore, we are assigning an interim final work RVU to CPT code 88374 of 0.93.

As discussed in the previous section, some of the add-on codes in this family had RUC-recommended work RVUs that were 60 percent of the work RVU of the base procedure and we applied that reduction to 88341. We believe this accurately reflects the resources used in furnishing these add-on codes. Accordingly, we used this methodology to establish interim final work RVUs of 0.53 for code 88364 (60 percent of the work RVU of CPT code 88365); 0.53 for CPT code 88369 (60 percent of the work RVU of CPT code 88368); and 0.43 for CPT code 88373 (60 percent of the work RVU of CPT code 88367).

(17) Electro-oculography (EOG VNG) CPT Codes 92270, 92540, 92541, 92542, 92544, 92543, and 92545)

After the RUC identified CPT code 92543 as potentially misvalued through the CMS-Other Source – Utilization over 250,000 screen, CPT revised the parentheticals for this code for CY 2015. We received RUC recommendations for CY 2015 for this code and other codes in the family. We are assigning the RUC-recommended work values for CPT codes 92270, 92540, 92541, 92542, 92544, and 92545. For CPT code 92543, however, we have been informed by the RUC that survey respondents may not have understood the revised code description for CPT code 92543, and thus the survey data may be unreliable. As a result, we believe the most accurate information upon which to base work RVUs for CPT code 92543 is its existing work RVU. Therefore, we are establishing a work RVU of 0.10 for CPT code 92543 as interim final for CY 2015.

(18) Interventional Transesophageal Echocardiography (TEE) (CPT Codes 93312, 93313, 93314, 93315, 93316, 93317, 93318, 93355, and 93644)

For CY 2015, CPT code 93355 was created to describe transesophageal echocardiography during interventional cardiac procedures. The RUC provided recommendations for CPT code 93355, and for CPT codes 93312-93318 in order to ensure intra-

family relativity. We are establishing the RUC-recommended work RVU of 2.40 as interim final for CY 2015 for CPT code 93318 and 4.66 for CPT code 93355.

The RUC based the work RVU for CPT code 93312 upon a crosswalk to CPT code 43247 (Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body). This code has significant differences from CPT code 93312. We have been unable to identify a CPT code with 30 minutes of intraservice time and 60 minutes of total time with a work RVU higher than 2.55. We believe this service is more similar to CPT code 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed) since it has similar work, time and the same global period. Based upon this crosswalk, we are assigning CPT code 93312 a CY 2015 interim final work RVU of 2.55.

Due to CPT descriptor for CPT code 93315, we believe that the appropriate work for this service is 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 are assigning CY 2015 interim final work RVUs based upon the 25th percentile values from the survey: 0.51 for CPT code 93313, 2.10 for CPT code 93314, 2.94 for CPT code 93315, 0.85 for CPT code 93316, 2.09 for CPT code 93317, and 4.66 for CPT code 93355. Each of these codes had a significant drop in intraservice time since the last valuation and RUC recommendations for higher work RVUs. As we have stated in the absence of information showing a change in intensity, we believe meaningful changes in time should be reflected in the work RVUs. For these codes, we believe the 25th percentile survey values better describe the work and time involved in these procedures than the RUC recommendations and also help maintain appropriate relativity in the family.

Additionally, we are refining 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.

(19) Subcutaneous Implantable Defibrillator Procedures (CPT Codes 33270, 33271, 33272, 33272, 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, 33272, 93260, 93261 and 93644. We received RUC recommendations for the new and revised codes. We are establishing the RUC-recommended work RVUs for all of the codes in this family except CPT code 93644. This code has an intraservice time of 20 minutes and a total time of 84 minutes. We disagree with the RUC-recommended crosswalk for CPT code 93644 which has an intraservice time of 29 minutes and a total time of 115 minutes and believe that a crosswalk to CPT code 32551 would be better as that code's intraservice time is 20 minutes and the total time is 83 minutes. Therefore, we are establishing a CY 2015 interim final work RVU of 3.29 for CPT code 93644.

(20) Duplex Scans (CPT Codes 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979)

In the CY 2013 PFS final rule with comment period, we requested that the RUC assess the relativity among the entire family of duplex scans codes and recommend appropriate work RVUs. CMS 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 in order to assess the relativity between and among those codes. The RUC reviewed this entire family of codes and provided recommendations for CY 2015. For CY 2015, we are establishing 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. We believe that this relationship between intraservice time and work RVU accurately reflects the time and intensity involved, and should be used for the majority of the codes in the family. As a result, for CPT codes 93926, 93979, and 93888, which all have 10 minutes of intraservice time, we are assigning an interim final work RVU of 0.50.

For several codes in this family with 15 minute of intraservice time, the RUC recommended work RVUs based upon the survey 25th percentile. We find this to appropriately reflect the work involved. Accordingly, for CPT codes 93975, 93976, and 93978, which all have 15 minutes of intraservice time, we are disagreeing with the RUC work RVU recommendations and assigning the 25th percentile of the survey as CY 2015 interim final values. Therefore, for CY 2015 we are establishing 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.
Lastly, we believe that the RUC recommendation for CPT code 93886 overvalues the work involved. We accepted the RUC recommendation for CPT code 93880 of 0.80 with an intraservice time of 15 minutes. CPT code 93886 has an intraservice time of 17 minutes. Applying the work RVU to time ratio of CPT code 93880 to the intraservice time of CPT code 93886 (results in our interim final value of 0.91 for CPT code 93886.

(21) Carotid Intima-Media Thickness Ultrasound (CPT Code 93895)

For CY 2015, a new code, CPT code 93895, describes the work of using carotid ultrasound to measure atherosclerosis and quantify the intima-media thickness. After review of this code, we determined that it is used only for screening and therefore, we are assigning a PFS procedure status indicator of N (Noncovered service) to CPT code 93895.

(22) Doppler Flow Testing (CPT Code 93990)

For CY 2015, the RUC provided a recommendation for CPT code 93990 which had been identified through the High Volume Growth Services where Medicare utilization increased by at least 100 percent from 2006 to 2011. The RUC recommended a work RVU of 0.60 for this service. Due to the similarity of this service to duplex scans, we are establishing RVUs for CPT code 93990 that are consistent with duplex scans with 10 minutes of intraservice time; which we discussed above in section E.4.18. We assigned it an interim final work RVU of 0.50.

(23) 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. It is unclear to us why CPT code 95973, the add-on code to CPT code 95972, was not also surveyed. We are valuing CPT code 95971 based upon the RUC recommended work RVU of 0.78.

For CPT code 95972, we do not believe that the RUC recommended change in work RVU from 1.50 to 0.90 reflects the much more significant change in intraservice time from 60 minutes to 23 minutes. Therefore, we used a building block methodology to develop a work RUV of 0.80.

Even though the RUC did not survey 95973, we believe we should review it as part of this family. Not having a survey or RUC recommendations, we believe that the percent decrease in the work RVU from the base code 95972 should apply to this code. Therefore, we are establishing an interim final work RVU of 0.49 for CPT code 95973.

We note that the descriptor for CPT code 95972 was changed from "…first hour" to "…up to one hour." We note that for Medicare purposes this code should only be billed when a

majority of an hour is completed. We would also note that the add-on code should only be reported after a full 60 minutes of service is furnished.

The lack of a survey for CPT code 95973 along with the confusing descriptor language and intraservice time suggest the need for this family to be returned to CPT for clarification of the descriptor and then to the RUC for resurvey.

(24) Negative Pressure Wound Therapy (CPT Codes 97607, and 97608, and HCPCS codes G0456 and G0457)

Prior to CY 2013, the codes used to report negative pressure wound therapy were CPT codes 97605 and 97606, both of which were typically reported in conjunction with durable medical equipment that was paid separately. 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, two new codes, CPT codes 97607 and 97608, were created 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 these the revised coding scheme for negative pressure wound therapy, we are deleting the

G-codes. We are contractor pricing these codes for CY 2015. CPT codes 97607 and 97608 will be designated "Sometimes Therapy" on our Therapy Code List, which is consistent with the G-codes. The Therapy Code List is available at http://www.cms.gov/Medicare/Billing/TherapyServices/index.html?redirect=/therapyservices."

(25) Application of Topical Fluoride Varnish (CPT Code 99188)

CPT Code 99188 is a new code for CY 2015 that describes the application of topical fluoride varnish to teeth. Since this code describes a service that involves the care of teeth, it is excluded from coverage under Medicare by section 1862(a)(12) of the Act, which provides "items and services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth are excluded from coverage." Accordingly, we are assigning a PFS procedure status indicator of N (Noncovered service) to CPT code 99188.

(26) Advance Care Planning (CPT codes 99497 and 99498)

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning 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-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)). For CY 2015, we are assigning a PFS 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. However, we will consider whether to pay for CPT codes

99497 and 99498 after we have had the opportunity to go through notice and comment rulemaking.

c. Establishing Interim Final Direct PE RVUs for CY 2015

i. Background and Methodology

The RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, disposable supplies, and medical equipment, for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs. This review is informed by both our clinical assessment of the typical resource requirements for furnishing the service and our intention to maintain the principles of accuracy and relativity in the database. We determine whether we agree with the RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required to furnish the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

We have accepted for CY 2015, as interim final and without refinement, the direct PE inputs based on the recommendations submitted by the RUC for the codes listed in Table 28. For the remainder of the RUC's direct PE recommendations, we have accepted the PE recommendations submitted by the RUC as interim final, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table 31.

We note that the final CY 2015 PFS direct PE input database reflects the refined direct PE inputs that we are adopting on an interim final basis for CY 2015. That database is available under downloads for the CY 2015 PFS final rule with comment period on the CMS website at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. We also note that the PE RVUs displayed in Addenda B and C reflect the interim final values and policies described in this section. All PE RVUs adopted on an interim final basis for CY 2015 are included in Addendum C and are open for comment in this final rule with comment period.

TABLE 28: CY 2015 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS	Short Descriptor
11980	Implant hormone pellet(s)
22512	Vertebroplasty addl inject
22515	Perq vertebral augmentation
22856	Cerv artific diskectomy
27280	Fusion of sacroiliac joint
31620	Endobronchial us add-on
33270	Ins/rep subq defibrillator
33271	Insj subq impltbl dfb elctrd
33272	Rmvl of subq defibrillator
33273	Repos prev impltbl subq dfb
33951	Ecmo/ecls insj prph cannula
33952	Ecmo/ecls insj prph cannula
33953	Ecmo/ecls insj prph cannula
33954	Ecmo/ecls insj prph cannula
33955	Ecmo/ecls insj ctr cannula
33956	Ecmo/ecls insj ctr cannula
33957	Ecmo/ecls repos perph cnula
33958	Ecmo/ecls repos perph cnula
33959	Ecmo/ecls repos perph cnula
33962	Ecmo/ecls repos perph cnula
33963	Ecmo/ecls repos perph cnula
33964	Ecmo/ecls repos perph cnula
33969	Ecmo/ecls rmvl perph cannula
33984	Ecmo/ecls rmvl prph cannula
33985	Ecmo/ecls rmvl ctr cannula
33986	Ecmo/ecls rmvl ctr cannula
33988	Insertion of left heart vent
33989	Removal of left heart vent
36818	Av fuse uppr arm cephalic
36819	Av fuse uppr arm basilic
36820	Av fusion/forearm vein
36821	Av fusion direct any site
36825	Artery-vein autograft
36830	Artery-vein nonautograft
36831	Open thrombect av fistula
36832	Av fistula revision open
36833	Av fistula revision
37218	Stent placemt ante carotid
43180	Esophagoscopy rigid trnso
52441	Cystourethro w/implant
55840	Extensive prostate surgery
55842	Extensive prostate surgery
55845	Extensive prostate surgery
58541	Lsh uterus 250 g or less
58542	Lsh w/t/o ut 250 g or less
58543	Lsh uterus above 250 g

HCPCS	Short Descriptor
58544	Lsh w/t/o uterus above 250 g
58570	Tlh uterus 250 g or less
58571	Tlh w/t/o 250 g or less
58572	Tlh uterus over 250 g
58573	Tlh w/t/o uterus over 250 g
64486	Tap block unil by injection
64487	Tap block uni by infusion
64488	Tap block bi injection
64489	Tap block bi by infusion
66179	Aqueous shunt eye w/o graft
66180	Aqueous shunt eye w/graft
66184	Revision of aqueous shunt
66185	Revise aqueous shunt eye
67036	Removal of inner eye fluid
67039	Laser treatment of retina
67040	Laser treatment of retina
67041	Vit for macular pucker
67042	Vit for macular hole
67043	Vit for membrane dissect
67255	Reinforce/graft eye wall
70496	Ct angiography head
70498	Ct angiography neck
76770	Us exam abdo back wall comp
76775	Us exam abdo back wall lim
76856	Us exam pelvic complete
76857	Us exam pelvic limited
77080	Dxa bone density axial
77316	Brachytx isodose plan simple
77317	Brachytx isodose intermed
77318	Brachytx isodose complex
88348	Electron microscopy
88356	Analysis nerve
91200	Liver elastography
92145	Corneal hysteresis deter
92541	Spontaneous nystagmus test
92542	Positional nystagmus test
92544	Optokinetic nystagmus test
92545	Oscillating tracking test
93260	Prgrmg dev eval impltbl sys
93261	Interrogate subq defib
93644	Electrophysiology evaluation
97610	Low frequency non-thermal us

ii. Common Refinements

Table 31 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this section, we discuss the general nature of some common refinements and the reasons for particular refinements.

(a) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in work time described in section II.E.3.a. of this final rule with comment period. We note that for many codes, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits included in the global periods result in corresponding changes to direct PE inputs. We also note that, for a significant number of services, especially diagnostic tests, the procedure time assumptions used in determining direct PE inputs are distinct from, and therefore not dependent on, work intraservice time assumptions. For these services, we do not make refinements to the direct PE inputs based on changes to estimated work intraservice times.

Changes in Intraservice Work Time in the Nonfacility Setting. For most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intraservice period reflects minutes assigned for assisting the practitioner with the procedure. To the extent that we are refining the times associated with the intraservice portion of such procedures, we have adjusted the corresponding intraservice clinical labor minutes in the nonfacility setting.

For equipment associated with the intraservice period in the nonfacility setting, we generally allocate time based on the typical number of minutes a piece of equipment is being used, and therefore, not available for use with another patient during that period. In general, we allocate these minutes based on the description of typical clinical labor activities. To the extent that we are making changes in the clinical labor times associated with the intraservice portion of procedures, we have adjusted the corresponding equipment minutes associated with the codes.

Changes in the Number or Level of Postoperative Office Visits in the Global Period. For codes valued with postservice office visits during a global period, most of the clinical labor time allocated to the postservice period reflects a standard number of minutes allocated for each of those visits. To the extent that we are refining the number or level of postoperative visits, we have modified the clinical staff time in the postservice period to reflect the change. We note that until the global periods are transitioned, consistent with other policies finalized in this rule, we will make these refinements. For codes valued with postservice office visits during a global period, we allocate standard equipment for each of those visits. To the extent that we are making a change in the number or level of postoperative visits associated with a code, we have adjusted the corresponding equipment minutes. For codes valued with postservice office visits during a global period, a certain number of supply items are allocated for each of those office visits. To the extent that we are making a change in the number of postoperative visits, we have adjusted the corresponding supply item quantities associated with the codes. We note that many supply items associated with postservice office visits are allocated for each office visit (for example, a minimum multi-specialty visit pack (SA048) in the CY 2015 direct PE input database). For these supply items, the quantities in the direct PE input database should reflect the number of office visits associated with the code's global period. However, some supply items are associated with postservice office visits but are only allocated once during the global period because they are typically used during only one of the postservice office visits (for example, pack, post-op incision care (suture) (SA054) in the direct PE input database). For these supply items, the quantities in the direct PE input database reflect that single quantity.

These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(b) Equipment Minutes

In general, the equipment time inputs reflect the sum of the times within the intraservice period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. In cases where equipment times included time for clinical labor activities in the pre-service period, we have refined these times to remove the minutes associated with these tasks, since the pre-service period ends "when patient enters office/facility for surgery/procedure." Although some services include equipment that is typically unavailable during the entire clinical labor service period, certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician for all tasks associated with a service, and therefore, are typically available for other patients during the preservice and postservice components of the service period. We adjust those equipment times accordingly. We refer interested stakeholders to our extensive discussion of these policies in the CY 2012 PFS final rule with comment period (76 FR 73182-73183) and in section II.G.2.b. of this final rule with comment period. We are refining the CY 2015 RUC direct PE recommendations to conform to these equipment time policies. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(c) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043-73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. In section II.A. of this final rule with comment period, we finalized a refinement to the standard package to include a stretcher for the same length of time as the other equipment items in the standard package. We are refining the CY 2015 RUC direct PE recommendations to conform to these policies. This includes the removal of a power table where it was included during the

intraservice period, as the stretcher takes the place of the table. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(d) Standard 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 recommended direct PE inputs on "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. At times, the RUC recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS reviews the deviations from the standards to assess whether they are clinically appropriate. Where the RUC-recommended exceptions are not accepted, we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M or other evaluation service, we remove the preservice clinical labor tasks so that the inputs are not duplicative and reflect the resource costs of furnishing the typical service.

In some cases the RUC recommendations include additional minutes described by a category called "other clinical activity," or through the addition of clinical labor tasks that are different from those previously included as standard. In these instances, CMS reviews the tasks as described in the recommendation to determine whether they are already incorporated into the total number of minutes based on the standard tasks. Additionally, CMS reviews these tasks in the context of the kinds of tasks delineated for other services under the PFS. For those tasks that are duplicative or not separately incorporated for other services, we do not accept those additional clinical labor tasks as direct inputs. For example, as we have previously discussed (78 FR 74308), we believe that quality assurance documentation tasks for services across the PFS are

already accounted for in the overall estimate of clinical labor time. We do not believe that it would serve the relativity of the direct PE input database were additional minutes added for each clinical task that could be discretely described for every code. These refinements are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(e) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended a new item be created and has facilitated CMS's pricing of that item by working with the specialty societies to provide sales invoices to us.

We received invoices for several new supply and equipment items for CY 2015. We have accepted the majority of these items and added them to the direct PE input database. Tables 29 and 30 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 reasonable. Where prices appear unreasonable, we encourage stakeholders to provide invoices that provide more accurate pricing for these items in the direct PE database. We remind stakeholders that due to the budget neutral nature of the PFS, increased prices for any items in the direct PE database decrease the pool of PE RVUs available to all other PFS services. Tables 29 and 30 also include the number of invoices received as well as the number of nonfacility allowed services for procedures that use these equipment items. In cases where large numbers of allowed services exist, we question pricing the item based upon a single invoice. We are

concerned that the single invoice may not be reflective of typical costs for these items and encourage stakeholders to provide additional invoices.

In some cases we cannot adequately price a newly recommended item due to inadequate information. In some cases, no supporting information regarding the price of the item has been included in the recommendation to create a new item. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, price quotes instead of paid invoices). In cases where the information provided allowed us to identify clinically appropriate proxy items, we have used existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without an associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the PE RVU for particular services, it facilitates our ability to incorporate a price once we are able to do so.

TABLE 29: INVOICES RECEIVED FOR NEW DIRECT PE INPUTS

CPT/HCPCS Codes	Item Name	CMS code	Average Price	Number of Invoices	Non-Facility Allowed Services for HCPCS Codes Using This Item (or Projected Services for New CPT Codes*)
20604, 20606, 20611	ultrasound transmission gel, sterile (single use)	SJ089	$1.71	1	748248*
22512	10g IVAS drill	SD292	$139.33	1	99*
22512	10g cannulae	SD293	$86.11	1	99*
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550	foam underwrap	SG097	$0.0043 per inch	1	415513
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550	rigid strapping tape (15 yards)	SG098	$0.018 per inch	1	415513
29200, 29240, 29260, 29280, 29520, 29530, 29540, 29550	skin prep barrier wipes	SM029	$0.20	1	415513
31620	Flexible dual-channeled EBUS bronchoscope, with radial probe	EQ361	$160,260.06	6	107

CPT/HCPCS Codes	Item Name	CMS code	Average Price	Number of Invoices	Non-Facility Allowed Services for HCPCS Codes Using This Item (or Projected Services for New CPT Codes*)
31620	Video system, Ultrasound (processor, digital capture, monitor, printer, cart)	ER099	$13,379.57	6	107
31620	EBUS, single use aspiration needle, 21 g	SC102	$145.82	5	107
31620	Balloon for Bronchosopy Fiberscope	SD294	$28.68	4	107
52441, 52442	Urolift Implant and implantation device	SD291	$775.00	10	12*
64486, 64488	ultrasound needle	SC101	$12.81	4	46851*
64487, 64489	continuous peripehral nerve block tray	SA116	$23.69	1	802*
77063	multimodality software	ED051	$11,570.00	12	297529*
88341	Anti CD45 Monoclonal Antibody	SL495	$3.61 per test	1	917673*
88344	34 Beta E12	SL496	$4.27 per test	1	51591*
88348	Digital Printer	ED048	$774.89	1	641
88348	Carbon Coater	EQ366	$22,540.08	1	641
88348	Diamond Milling Tool	EQ365	$1,714.00	1	641
88356, 88348	Electron Microscopy Tissue processor	EP115	$13,119.00	2	19134
88356, 88348	Block face milling machine	EQ363	$18,139.00	1	19134
88356, 88348	Glass Knife Breaker	EQ364	$9,585.14	1	19134
88364	CMV DNA Probe Cocktail	SL500	$0.10 per ul	1	3376*

CPT/HCPCS Codes	Item Name	CMS code	Average Price	Number of Invoices	Non-Facility Allowed Services for HCPCS Codes Using This Item (or Projected Services for New CPT Codes*)
88341, 88342, 88344, 88364, 88365, 88367, 88368, 88369, 88373	Universal Detection Kit	SA117	$4.00	1	1380597
88365	EBER positive control slide	SL507	$20.15	1	8440
88365	(EBER) DNA Probe Cocktail	SL497	$8.57 per test	2	8440
88365, 88366, 88367, 88368, 88374, 88377	VP-2000 Processor	EP116	$30,800.00	1	228243
88367, 88368	Kappa Probe Cocktails	SL498	$0.10 per ul	1	36634
88369, 88373	Lambda Probe Cocktail	SL499	$0.10 per ul	1	24423*
88380, 88381	Surface Decontaminant (DNA Away)	SL494	$0.07 per ml	1	6649
91200	Fibroscan	ER101	$124,950.00	1	87*
92145	Ocular Response Analyzer	EQ360	$12,000.00	3	Unknown
92541, 92542, 92544, 92545	VNG Recording System	EQ367	$29,607.50	2	101139
93702	BIS monitoring system (bioimpedance spectroscopy)	EQ359	$3,316.93	1	Unknown

CPT/HCPCS Codes	Item Name	CMS code	Average Price	Number of Invoices	Non-Facility Allowed Services for HCPCS Codes Using This Item (or Projected Services for New CPT Codes*)
93702	electrode, BIS (bioimpedance spectroscopy)	SD290	$28.33	1	Unknown
96127	Beck Youth Inventory, Second Edition (BYI-II); Combination Inventory Booklet	SK119	$1.96 per booklet	1	Unknown
97610	MIST Therapy System	EQ372	$28,000.00	2	2*
97610	MIST Therapy Cart	EQ368	$1,250.00	1	2*
97610	kit, low frequency ultrasound wound therapy (MIST)	SA119	$63.33	3	2*
99188	CavityShield 5% Varnish .25mL	SH106	$0.91	1	Unknown
G0277	HBOT air break breathing apparatus demand system (hoses, masks, penetrator and demand valve)	EQ362	$986.00	1	153044*

TABLE 30: INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS Codes	Item Name	CMS code	Current Price	Updated Price	% Change	Number of Invoices	Non-facility Allowed Services for HCPCS codes using this item
20983, 47383	cryosurgery system (for tumor ablation)	EQ302	missing	$37,500.00		2	22*
20983, 47383	gas, argon	SD227	$0.25 per cubic foot	$0.32 per cubic foot	28%	1	22*
20983, 47383	gas, helium	SD079	$0.25 per cubic foot	$0.57 per cubic foot	128%	1	22*
31627	system, navigational bronchoscopy (superDimension)	EQ326	$137,800.00	$189,327.66	37%	4	37
31627	kit, locatable guide, ext. working channel, w-b-scope adapter	SA097	$995.00	$1,063.67	7%	3	37
64561	kit, percutaneous neuro test stimulation	SA022	$305.00	$420.00	38%	1	8229
88348	camera, digital system, for electron microscopy	ED006	$41,000.00	$82,000.00	100%	1	641
88348, 88356	microtome, ultra	ER043	$25,950.00	$34,379.00	32%	1	19134
G0277	HBOT (hyperbaric oxygen therapy) monochamber, incl. gurney and integrated grounding assembly	EQ131	$125,000.00	$127,017.98	2%	1	153044*

*New procedure - Projected volume

(f) Recommended Items that are not Direct PE Inputs

In some cases, the recommended direct PE inputs included items that are not clinical labor, disposable supplies, or medical equipment resources. We have addressed these kinds of recommendations in previous rulemaking and in sections II.G.2.b. and II.B.4.a. of this final rule with comment period. Refinements to adjust for these recommended inputs are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

(g) Film-to-digital Migration

As discussed in section II.A.3 of this final rule with comment period, we are finalizing our policy to remove equipment and supply inputs associated with film technology from the direct PE database. Since the recommendations we received for 2015 were prepared before the transition occurred, in some cases, the RUC recommendations included film inputs. Where recommendations included these inputs, we have removed these inputs and replaced them with "PACS workstation proxy" as described in section II.A.3 of this final rule with comment period. Since the film-to-digital transition results from our acceptance of a RUC recommendation, we do not consider the removal of these items to be refinements of RUC recommendations, and therefore do not include them in Table 31.

(h) Pre-service and post-service tasks for Add-on codes

In general, we believe that certain pre-service and post-service tasks are not repeated for services reported using add-on codes. In some cases, we also believe that the time for certain equipment items are not duplicated for add-on codes. In these cases, we removed the time associated with those tasks and/or equipment items from those codes. These refinements appear in Table 31.

iii. Code-Specific Refinements

(a) Rib Fractures (CPT codes 21811, 21812, and 21813)

For the newly created rib fracture codes, which are frequently furnished as emergency surgeries, the RUC did not include time for the standard pre-service activities "Provide pre-service education/obtain consent" and "Follow-up phone calls & prescriptions." However, the RUC recommendation included time for pre-service activities "Complete pre-service diagnostic & referral forms," "Coordinate pre-surgery services", and "Schedule space and equipment in facility." Since these codes would typically be provided as emergency surgeries, we question whether these tasks would typically be performed.

We reviewed other emergency procedures in the PFS to determine whether pre-service clinical labor activities were typically included in the PE worksheets. We found that the recommendations for these procedures were inconsistent. Therefore, we will not remove the time allocated for these clinical labor activities at this time. However, we believe that for emergency procedures, none of the pre-service tasks listed above would typically be performed. We seek comment to clarify this issue, and plan to consider this issue in future rulemaking.

As discussed earlier in this section of this final rule with comment period, we have valued CPT codes 21811, 21812, and 21813 as 0-day globals. We have therefore removed direct PE inputs associated with the postoperative visits.

(b) Percutaneous Vertebroplasty and Augmentation (CPT codes 22510, 22511, 22512, 22513, 22514, and 22515)

The RUC recommendation regarding add-on CPT code 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)) included new supply item "10g IVAS drill." We note that the recommendations for the base codes did not contain this supply item, and the vertebroplasty kit does not appear to

contain this drill either. We do not understand why the drill would be required for the add-on code when it is not required for the base code. Therefore, we will not include supply item "10g IVAS drill" in CPT code 22512 at this time.

(c) Endobronchial Ultrasound (EBUS) (CPT code 31620)

As indicated earlier in this section of this final rule with comment period, we are maintaining the CY 2014 work RVU for CPT code 31620 in light of our concerns regarding coding structure. As such, we are maintaining the CY 2014 direct PE inputs for 31620 as well.

(d) Breast Tomosynthesis (CPT codes 77061, 77062, and 77063)

For CY 2015, the CPT Editorial Panel created three codes to describe digital breast tomosynthesis services: 77061(Digital breast tomosynthesis; unilateral), 77062 (Digital breast tomosynthesis; bilateral) and 77063 (Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)). For these newly created codes, the RUC recommended creating a new equipment item, "room, breast tomosynthesis", at a price of $667,669, as well as a list of items contained in the room. We believe that several of the items included in the room are not appropriately characterized as direct costs. We also believe that the creation of rooms sometimes causes confusion when items in the room are also included as stand-alone PE inputs, as specialty societies do not consider the items included in the room when preparing the PE worksheets. Further, we believe that the prices for the rooms sometimes result in less transparency, as prices for items within the room tend to remain static over time. Therefore, we are not creating this new equipment item, but will instead include the individual equipment items that we believe are appropriately characterized as direct costs.

The price for the digital breast tomosynthesis unit indicated on the invoice received by the RUC was $498,412. We received many invoices for this equipment item with an average price of $381,380. Therefore, we will create a new equipment item "DBT unit", at a price of

$381,380.

The RUC also recommended including a new equipment item, "PACS cache", for these procedures. We do not believe that digital storage constitutes a direct cost, as it is not individually allocable to an individual patient for a particular service. . Therefore, we will not add this new equipment item to the direct PE database.

(e) Radiation Treatment (CPT codes 77385, 77386, 77387, 77402, 77407, 77412)

For CY 2015, the CPT Editorial Panel revised the set of codes that describe radiation treatment delivery services. These revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. Due to the significant code restructuring and potential for changes in payment, some specialty societies representing providers of radiation treatment services have requested that we delay implementation of the new code set. We believe that given the large scale of the changes in this code set restructuring, in the context of our upcoming revised process for valuing new, revised, and potentially misvalued codes, it is prudent to propose the values for the revised code set in the CY 2016 rule with opportunity for public comment prior to establishing payment rates.

(f) Immunohistochemistry (CPT codes 88341, 88342, and 88344)

The RUC recommended including supply item "UltraView Universal DAB Detection Kit" (SL488) for CPT codes 88341, 88342, and 88344, which is priced at $10.49 per kit, and "UltraView Universal Alkaline Phosphatase Red Detection Kit", which is priced at $20.64. We noted that for other similar services, CPT codes 88364, 88365, 88367, 88368, 88369, and 88373, the RUC recommended including supply item "Universal Detection Kit" (SA117), which is priced at $4.00 per kit. After reviewing information about these two kits, we believe that functions provided by SL488 and SL489 are also provided by SA117. The recommendations did not explain why the more expensive kit was necessary for 88341, 88342, and 88344 when the

less expensive kit was sufficient for CPT codes 88364, 88365, 88367, 88368, 88369, and 88373. Absent any rationale for the use of the more expensive kit, we are including SA117 for 88341, 88342, and 88344 in place of SL488.

(g) Electron Microscopy (CPT code 88348)

The RUC recommended including a new supply item, "diamond milling tool", for use with CPT code 88348. However, upon reviewing the invoice, we believe that "diamond milling tool" is more appropriately characterized as equipment. We have therefore created an equipment item for this tool, as listed in Table 29.

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

The CPT Editorial Panel revised the in situ hybridization codes (88365, 88367, and 88368) and created three new add-on codes for reporting each additional separately identifiable probe per slide. The RUC reviewed CPT codes 88365, 88367, and 88368, among other services in this family, in October 2013 and recommended direct inputs for these procedures, including supply item "kit, FISH paraffin pretreatment" (SL195), with quantities of 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and 1 unit for CPT code 88368.

After the CY 2014 PFS final rule with comment period was published, the specialty societies determined that additional clarification was necessary, and requested that the CPT Editorial Panel review the entire family again. The CPT editorial panel added three new codes for "each multiplex probe stain procedure." The specialty societies then resurveyed these procedures. The RUC reviewed the entire family at the April 2014 meeting and recommended supply item SL195 with a quantity of 2 units for CPT code 88365, 1.4 units for CPT code 88367, and 2 units for CPT code 88368. These quantities are double what the RUC recommended to us in October 2013, which was 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and one

unit for CPT code 88368. Without an explanation for this significant change, we are including SL195 with the following quantities: 1 unit for CPT code 88365, 0.75 units for CPT code 88367, and 1 unit for CPT code 88368. Similarly, for add-on services CPT codes 88364, 88366, 88369, 88373, 88374, and 88377, more than one unit of SL195 was included. We believe that the unit of the kit should be consistent between the base code and the add-on code. We will therefore include 1 unit of SL195 for CPT codes 88364, 88366, 88369, and 88377, and 0.75 units for CPT codes 88373 and 88374. We are also interested in learning more about why a partial kit would be used in furnishing the typical service.

CPT codes 88374 and 88377, which are add-on codes, contain more than one unit of supply item "kit, HER-2/neu DNA Probe" (SL196). Because these codes describe a service that includes a single specimen with one stain, we do not understand why more than one kit would be required. We have therefore included a unit of 1 for SL196 in CPT codes 88374 and 88377.

We also believe that the units of positive control slides and negative control slides should be consistent throughout this entire family. We note that CPT codes 88367, 88373, and 88374 included a recommended 0.2 units of positive and/or negative control slide; supply items SL118 and SL119 for CPT code 88367, supply items SL120 and SL121 for CPT code 88373, and supply items SL184 and SL185 for CPT code 88374.) However, for CPT codes 88368, 88369, and 88377, the recommendation included 0.5 units of the positive and/or negative control slide (supply item SL112 for CPT codes 88368 and 88369, and supply items SL184 and SL185 for CPT code 88377). No rationale was provided for why a greater quantity of the control slide would be required. Therefore, we will include 0.2 units of positive and/or negative control slides, as appropriate, to maintain consistency throughout this family of codes.

As with the positive and negative control slides, we believe that the number of units of supply item SL498 ("Kappa probe cocktails") and SL499 (Lambda probe cocktails") should be

consistent across procedures. The recommendations for CPT codes 88367 and 88373 contain 28 ul of SL498 for 88367 and 27 ul of SL499 for 88373. Therefore, to maintain consistency, we refined the units of SL498 for CPT code 88368 and SL499 for CPT code 88369 to 28 ul.

The RUC recommended a quantity of 1.6 for SL497 "(EBER) DNA Probe Cocktail" for CPT code 88365. Since this procedure describes a single stain, and the stain needs to be added to the positive control slide and the specimen slide, we believe that a quantity of 2 is more appropriate. We have therefore included 2 units of SL497 for CPT code 88365.

The RUC recommendation also included a new equipment item "VP-2000 processor" (EP116). Among the purposes of this equipment item is to reduce the amount of technician time needed to complete the clinical labor task. However, in the recommendations we received, rather than the clinical labor time for these codes decreasing with the addition of this new equipment item, the RUC recommended increased clinical labor times associated with this task for CPT codes 88365, 88366, 88368, and 88377 increased. We are unable to reconcile as typical the new equipment item, which is intended to reduce technician time, with the increased technician time for this same clinical labor task. Therefore, we will not allocate time for equipment item "VP-2000 processor" (EP116) in CPT codes 88365, 88366, 88368, and 88377.

(h) 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 do not believe that both the pathologist and the cytotechnologist are completing these tasks, we have refined out the lines associated with the specific tasks we believe are completed by the pathologist. Table 31 details our refinements to the clinical labor tasks.

(j) Interventional Transesophageal Echocardiography (TEE) (CPT codes 93312 and 93314)

CPT code 93314 describes a service in which the acquisition and interpretation of images is furnished by a different practitioner than the placement of the probe. CPT code 93312 includes all services encompassed by CPT code 93314 and included a recommendation for 30 minutes of assist physician time. We do not believe that CPT code 93314 should have more clinical labor than CPT code 93312, which is the more extensive code. We have therefore refined this time to 30 minutes, which is the same as the time allocated to 93312. We also note that the time allocated to equipment item "room, ultrasound, vascular" (EL016) was affected by this refinement.

(k) Hyperbaric Oxygen Therapy (HBOT) (HCPCS code G0277)

We received a RUC recommendation for CPT code 99183 (Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session), which included significant increases to the direct PE inputs, which assumes a treatment time of 120 minutes. Currently, CPT code 99183 is used for both the professional attendance and supervision and the actual treatment delivery. Stakeholders have pointed out that although we include the PE inputs for treatment delivery in this code, the descriptor describes only attendance and supervision. We note that under the OPPS, the treatment is reported using separate treatment code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval). After considering this issue, we believe the OPPS approach would also be appropriate for the PFS. We are therefore creating a G-code to report the treatment delivery and to maintain consistency with the OPPS coding. We will use the same descriptor as previously used for OPPS code C1300 for a timed 30-minute code, which can then be used across settings. To value this G-code, we used the RUC recommended direct PE inputs for 99183 and adjusted them to align with the 30 minute treatment interval.

In reviewing the recommended direct PE inputs, 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 provide 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.

(l) EOG VNG (CPT code 92543)

As described earlier in this section of this final rule with comment period, we are maintaining the CY 2014 work RVU for CPT code 92543 due to possible confusion among survey respondents. Similarly, we are also maintaining the CY 2014 direct PE inputs for 92543.

These refinements, as well as other applicable standard and common refinements for these codes, are reflected in the final CY 2015 PFS direct PE input database and detailed in Table 31.

TABLE 31: CY 2015 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
20604	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
20606	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
20611	Drain/inj joint/bursa w/us	L037D	RN/LPN/MTA	F	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
		L037D	RN/LPN/MTA	NF	Conduct phone calls/call in prescriptions	3	0	Typically billed with an E/M service	$-1.11
20983	Ablate bone tumor(s) perq	EF018	stretcher	NF		60	193	Standard equipment and time for moderate sedation	$0.68
		EF027	table, instrument, mobile	NF		134	193	Standard equipment and time for moderate sedation	$0.08
		EL007	room, CT	NF		134	133	Refined equipment time to conform to established policies for highly technical equipment.	$-4.87
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		194	193	Standard equipment and time for moderate sedation	$-0.01

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		EQ032	IV infusion pump	NF		194	193	Standard equipment and time for moderate sedation	$-0.01
		EQ168	light, exam	NF		194	133	Refined equipment time to conform to established policies for non-highly technical equipment.	$-0.26
		EQ302	cryosurgery system (for tumor ablation)	NF		134	133	Refined equipment time to conform to established policies for highly technical equipment.	$-0.10
21811	Optx of rib fx w/fixj scope	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	$-4.44
		EF014	light, surgical	PO		72	0	Post-operative visits removed; see preamble text.	$-0.72
		EF031	table, power	PO		72	0	Post-operative visits removed; see preamble text.	$-1.18
		SA048	pack, minimum multi-specialty visit	PO		2	0	Post-operative visits removed; see preamble text.	$-2.29
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	$-5.06
21812	Treatment of rib fracture	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	$-4.44
		EF014	light, surgical	PO		99	0	Post-operative visits removed; see preamble text.	$-0.99
		EF031	table, power	PO		99	0	Post-operative visits removed; see preamble text.	$-1.62
		SA048	pack, minimum multi-specialty visit	PO		3	0	Post-operative visits removed; see preamble text.	$-3.43

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	$-5.06
21813	Treatment of rib fracture	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Post-operative visits removed; see preamble text.	$-4.44
		EF014	light, surgical	PO		99	0	Post-operative visits removed; see preamble text.	$-0.99
		EF031	table, power	PO		99	0	Post-operative visits removed; see preamble text.	$-1.62
		SA048	pack, minimum multi-specialty visit	PO		3	0	Post-operative visits removed; see preamble text.	$-3.43
		SA052	pack, post-op incision care (staple)	PO		1	0	Post-operative visits removed; see preamble text.	$-5.06
22513	Perq vertebral augmentation	SA053	pack, post-op incision care (suture & staple)	NF		1	0	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	$-6.11
		SA054	pack, post-op incision care (suture)	NF		0	1	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	$4.91
22514	Perq vertebral augmentation	SA053	pack, post-op incision care (suture & staple)	NF		1	0	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	$-6.11
		SA054	pack, post-op incision care (suture)	NF		0	1	No justification provided for use of staple and suture pack. Suture pack sufficient in the typical procedure.	$4.91

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
27279	Arthrodesis sacroiliac joint	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	6	Aligned clinical labor discharge day management time with the work time discharge day code.	$-2.22
29200	Strapping of chest	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29240	Strapping of shoulder	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29260	Strapping of elbow or wrist	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29280	Strapping of hand or finger	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29520	Strapping of hip	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29530	Strapping of knee	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29540	Strapping of ankle and/or ft	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
29550	Strapping of toes	L023A	Physical Therapy Aide	NF	Greet patient and provide gowning	3	0	Typically billed with an E/M or other evaluation service	$-0.69
31627	Navigational bronchoscopy	EF027	table, instrument, mobile	NF		45	30	Standard equipment and time for moderate sedation	$-0.02
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		45	30	Standard equipment and time for moderate sedation	$-0.21

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		EQ032	IV infusion pump	NF		45	30	Standard equipment and time for moderate sedation	$-0.09
		L047C	RN/Respiratory Therapist	NF	Prepare and position pt/ monitor pt/ set up IV	2	0	Add-on code; no additional time required to prepare and position patient	$-0.94
33418	Repair tcat mitral valve	L037D	RN/LPN/MTA	F	Discharge day management 99238 --12 minutes	12	0	Aligned clinical labor discharge day management time with the work time discharge day code.	$-4.44
		L037D	RN/LPN/MTA	F	Discharge day management 99239 -- 15 minutes	0	15	Aligned clinical labor discharge day management time with the work time discharge day code.	$5.55
33965	Ecmo/ecls rmvl perph cannula	L051A	RN	F	Schedule space and equipment in facility	0	5	Standard inputs for procedures with 90 day global periods	$2.55
33966	Ecmo/ecls rmvl prph cannula	L051A	RN	F	Schedule space and equipment in facility	0	5	Standard inputs for procedures with 90 day global periods	$2.55
36475	Endovenous rf 1st vein	EF019	stretcher chair	NF		30	31	Refined equipment time to conform to clinical labor time.	$0.01
36476	Endovenous rf vein add-on	EL015	room, ultrasound, general	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	$-2.80
		EQ215	radiofrequency generator (vascular)	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	$-0.19
		L054A	Vascular Technologist	NF	Review examination with interpreting MD	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	$-0.54

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		L054A	Vascular Technologist	NF	Technologist QCs images US machine, checking for all images, reformats, and dose page	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	$-0.54
36478	Endovenous laser 1st vein	EF019	stretcher chair	NF		30	31	Refined equipment time to conform to clinical labor time.	$0.01
36479	Endovenous laser vein addon	EL015	room, ultrasound, general	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	$-2.80
		EQ160	laser, endovascular ablation (ELVS)	NF		32	30	Refined equipment time to conform to changes in clinical labor time.	$-0.33
		L054A	Vascular Technologist	NF	Review examination with interpreting MD	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	$-0.54
		L054A	Vascular Technologist	NF	Technologist QCs images US machine, checking for all images, reformats, and dose page	1	0	Add-on code; no additional time required for clinical labor tasks associated with digital imaging	$-0.54
47383	Perq abltj lvr cryoablation	EF018	stretcher	NF		240	166	Standard equipment and time for moderate sedation	$-0.39
		EF027	table, instrument, mobile	NF		104	166	Standard equipment and time for moderate sedation	$0.09
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		164	166	Standard equipment and time for moderate sedation	$0.03
		EQ032	IV infusion	NF		164	166	Standard equipment and time	$0.01

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			pump					for moderate sedation	
		EQ168	light, exam	NF		164	106	Refined equipment time to conform to established policies for non-highly technical equipment.	$-0.25
52442	Cystourethro w/addl implant	EF027	table, instrument, mobile	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	$0.04
		EF031	table, power	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	$0.41
		EQ170	light, fiberoptic headlight w-source	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	$0.20
		ES018	fiberscope, flexible, cystoscopy	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	$1.07
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		0	25	No equipment times were included; aligned equipment time with assist physician time.	$3.22
62284	Injection for myelogram	EF018	stretcher	NF		60	48	Refined equipment time to conform to established policies for non-highly technical equipment.	$-0.06

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62302	Myelography lumbar injection	L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	26	13	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$-4.81
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	13	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$5.33
62303	Myelography lumbar injection	EF018	stretcher	NF		60	64	Refined equipment time to conform to established policies for non-highly technical equipment.	$0.02
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	25	13	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$-4.44
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	12	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$4.92
62304	Myelography lumbar injection	EF018	stretcher	NF		60	59	Refined equipment time to conform to established policies for non-highly technical equipment.	$-0.01
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	25	13	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$-4.44
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	12	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$4.92
62305	Myelography lumbar injection	EF018	stretcher	NF		60	64	Refined equipment time to conform to established policies for non-highly	$0.02

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								technical equipment.	
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	15	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$-5.55
		L041B	Radiologic Technologist	NF	Assist physician in performing procedure	0	15	All clinical labor activities were assgined to L037D. Reassigned imaging tasks to L041B.	$6.15
64561	Implant neuroelectrodes	EQ202	percutaneous neuro test stimulator	NF		0	65	Neuro test stimulator is required to complete Percutaneous implanation of neurostimulator	$0.17
		SB012	drape, sterile, for Mayo stand	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	$-1.69
		SG074	steri-strip (6 strip uou)	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	$-1.12
		SJ043	povidone swabsticks (3 pack uou)	NF		1	0	Duplicative; Item included in percutaneous neuro test stimulation kit (SA022).	$-0.41
70486	Ct maxillofacial w/o dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.41

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70487	Ct maxillofacial w/dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.41
		L046A	CT Technologist	NF	SVC Provide pre-service education/obtain consent	3	2	CT Angiography only requires 2 minutes for this task; maintain consistency within family	$-0.46
70488	Ct maxillofacial w/o & w/dye	L041B	Radiologic Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.41
		L046A	CT Technologist	NF	SVC Provide pre-service education/obtain consent	3	2	CT Angiography only requires 2 minutes for this task; maintain consistency within family	$-0.46
74174	Ct angio abd&pelv w/o&w/dye	L046A	CT Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.46
76641	Ultrasound breast complete	EL015	room, ultrasound, general	NF		30	27	Refined equipment time to conform to established policies for highly technical equipment.	$-4.21

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76642	Ultrasound breast limited	EL015	room, ultrasound, general	NF		28	20	Refined equipment time to conform to established policies for highly technical equipment.	$-11.21
		L046A	CT Technologist	NF	Acquire images	15	10	Limited study takes less time to complete than complete study; used ratio of ultrasound abdomen complete and limited to adjust 15 to 10 minutes.	$-2.30
76942	Echo guide for biopsy	L051B	RN/Diagnostic Medical Sonographer	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.51
77061	Breast tomosynthesis uni	L043A	Mammography Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.43
77062	Breast tomosynthesis bi	L043A	Mammography Technologist	NF	Availability of prior images confirmed	3	2	Standard times for clinical labor tasks associated with digital imaging	$-0.43
77063	Breast tomosynthesis bi	L043A	Mammography Technologist	NF	Federally Mandated MQSA Activities Allocated To Each Mammogram	4	0	Add-on code; no additional time required for this task.	$-1.72
77085	Dxa bone density study	ER019	densitometry unit, fan beam, DXA (w-computer hardward & software)	NF		38	34	Refined equipment time to conform to changes in clinical labor time.	$-1.29
		L041B	Radiologic Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	6	2	Standard times for clinical labor tasks associated with digital imaging	$-1.64

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77086	Fracture assessment via dxa	ER019	densitometry unit, fan beam, DXA (w-computer hardward & software)	NF		21	19	Refined equipment time to conform to changes in clinical labor time.	$-0.64
		L041B	Radiologic Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	2	Standard times for clinical labor tasks associated with digital imaging	$-0.82
77300	Radiation therapy dose plan	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	$-3.10
77306	Telethx isodose plan simple	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	$-3.10
77307	Telethx isodose plan cplx	ED011	computer system, record and verify	NF		5	0	Item was not previously included for this service; rationale for change not provided. See 78 FR 74317 for further discussion.	$-3.10
88341	Immunohisto antibody slide	EP024	microscope, compound	NF		21	13	Decreased physician work for 88341 to 60% of 88342; same adjustment was made for equipment used by physician.	$-0.30
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02

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		SA117	Universal Detection Kit	NF		0	2	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$8.00
		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$-20.97
88342	Immunohisto antibody stain	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		SA117	Universal Detection Kit	NF		0	2	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$8.00
		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$-20.97
88344	Immunohisto antibody slide	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		EP112	Benchmark ULTRA automated slide preparation system	NF		33	30	Multiplex service - 2 stains is typical; since single stains requires 15 minutes, 2 stains requires no more than 30 minutes	$-1.52
		SA117	Universal Detection Kit	NF		0	4	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$16.00

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		SL488	UltraView Universal DAB Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$-20.97
		SL489	UtraView Universal Alkaline Phosphatase Red Detection Kit	NF		2	0	Maintain consistency in the type of universal detection kit with remaining code-sets within this family.	$-41.28
88364	Insitu hybridization (fish)	EP024	microscope, compound	NF		37	22	Decreased physician work for 88341 to 60% of 88342; same adjustment was made for equipment used by physician.	$-0.56
		EP045	chamber, hybridization	NF		240	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	$-5.51
		EP054	water bath, FISH procedures (lab)	NF		13	0	Add on code. Water bath is used concurrently for the base code and add-on code	$-0.09
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		L037B	Histotechnologist	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	0.5	0	Add-on code. Additional clinical labor time for post-service task not required. See preamble.	$-0.19
		SB023	gloves, non-sterile, nitrile	NF		0.25	0	Add-on code. Gloves are not changed between base code	$-0.05

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								and add-on code	
		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08
88365	Insitu hybridization (fish)	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	$-2.90
		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08

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		SL497	(EBER) DNA Probe Cocktail	NF		1.6	2	Stain needs to be added to the positive control slide and the specimen slide. See preamble.	$3.43
88366	Insitu hybridization (fish)	EP088	ThermoBrite	NF		2.5	0	This input is not contained within any other code in this family. Maintaining consistency with all other codes within family.	$-0.05
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	$-2.90
		L037B	Histotechnologist	NF	Examine signals in each cell and generate data for the pathologist to interpret	20	15	Refined clinical labor time for this multiplex procedure to reflect efficiencies in examining two stains on a single slide.	$-1.85
		SL189	ethanol, 100%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-20.85
		SL248	ethanol, 95%	NF		62.5	37.5	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.08
88367	Insitu hybridization	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a	$-0.02

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	auto							particular patient for a particular service	
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	No rationale provided for quantity change. See preamble.	$-13.55
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04
88368	Insitu hybridization manual	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	$-2.90
		SL508	positive control slide (proxy for Kappa Positive Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-3.54
		SL509	positive control slide (proxy for Kappa Negative Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-3.54
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.06

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		SL190	ethanol, 70%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.02
		SL191	ethanol, 85%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.02
		SL195	kit, FISH paraffin pretreatment	NF		2	1	No rationale provided for quantity change. See preamble.	$-20.85
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.06
		SL498	Kappa Probe Cocktail	NF		40	28	Maintain consistency in unit of probe cocktails within this family of codes. See preamble.	$-1.14
88369	M/phmtrc alysishquant/se miq	EP024	microscope, compound	NF		42	25	Refined equipment time for this multiplex procedure to reflect efficiencies in time when examining two stains on a single slide.	$-0.64
		EP045	chamber, hybridization	NF		240	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	$-5.51
		EP054	water bath, FISH procedures (lab)	NF		13	0	Add on code. Water bath is used concurrently for the base code and add-on code	$-0.09
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02

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		L037B	Histotechnologist	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	0.5	0	Add-on code. Additional clinical labor time for post-service task not required. See preamble.	$-0.19
		SB023	gloves, non-sterile, nitrile	NF		0.25	0	Not necessary to change gloves between the slides in the same procedure.	$-0.05
		SL510	positive control slide (proxy for Lambda Positive Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-3.54
		SL511	positive control slide (proxy for Lambda Negative Control Slide)	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-3.54
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.06
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-20.85
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.06

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		SL499	Lambda Probe Cocktail	NF		40	28	Maintain consistency in unit of probe cocktails within this family of codes. See preamble.	$-1.14
88373	M/phmtrc alys ishquant/semiq	EP024	microscope, compound	NF		42	25	Refined equipment time for this multiplex procedure to reflect efficiencies in time when examining two stains on a single slide.	$-0.64
		EP045	chamber, hybridization	NF		120	0	Add-on code. Base code includes the hybridization chamber, which would be used concurrently for both stains	$-2.75
		EP054	water bath, FISH procedures (lab)	NF		7	0	Add on code. Water bath is used concurrently for the base code and add-on code	$-0.05
		EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		SB023	gloves, non-sterile, nitrile	NF		0.125	0	Not necessary to change gloves between the slides in the same procedure.	$-0.02
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-13.55
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04

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88374	M/phmtrc alys ishquant/semiq	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		SL030	cover slip, glass	NF		2.8	1.4	Quantity of slides required for this multiplex procedure does not differ from the single procedure (only number of stains per slide differs).	$-0.11
		SL189	ethanol, 100%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04
		SL195	kit, FISH paraffin pretreatment	NF		1.4	0.75	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-13.55
		SL196	kit, HER-2/neu DNA Probe	NF		2.4	1	A single kit is required for this procedure which involves a single specimen with one stain.	$-147.00
		SL248	ethanol, 95%	NF		31.25	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.04
88377	M/phmtrc alys ishquant/semiq	EP110	Freezer	NF		1	0	Indirect Practice Expense. Not individually allocable to a particular patient for a particular service	$-0.02
		EP116	VP-2000 Processor	NF		30	0	We are unable to reconcile the new equipment item with the increased technician time. See preamble.	$-2.90

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		L037B	Histotechnologist	NF	Signal Enumeration: Count signals in malignant cells and generate data for pathologist to interpret	24	18	Refined clinical labor time for this multiplex procedure to reflect efficiencies in examining two stains on a single slide.	$-2.22
		SL184	slide, negative control, Her-2	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-8.82
		SL185	slide, positive control, Her-2	NF		0.5	0.2	Maintain consistency in unit of control slides within family of codes. See preamble.	$-8.82
		SL189	ethanol, 100%	NF		37.5	18.75	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.06
		SL190	ethanol, 70%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.02
		SL191	ethanol, 85%	NF		12.5	6.25	No rationale was provided for quantity change relative to current value. Maintaining current value.	$-0.02
		SL195	kit, FISH paraffin pretreatment	NF		2	1	Maintain consistency in unit of the kit between base code and add-on code. See preamble.	$-20.85
		SL196	kit, HER-2/neu DNA Probe	NF		3	1	A single kit is required for this procedure which involves a single specimen with one stain.	$-210.00
		SL248	ethanol, 95%	NF		37.5	18.75	No rationale was provided for quantity change relative to	$-0.06

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								current value. Maintaining current value.	
88380	Microdissection laser	EP087	instrument, microdissection (Veritas)	NF		34	32	Since physician is doing this task, equipment time was calculated by summing physician intraservice time, time to set up machine, and time to clean machine.	$-1.36
		L045A	Cytotechnologist	NF	Dispose of razor blade, Cap tube and vortex specimens. Visually inspect tube to make sure microdissected material are at the bottom of tube.	3	0	Included in clinical labor task "clean room, equipment, and supplies"	$-1.35
		L045A	Cytotechnologist	NF	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	18	0	Work vignette indicates that the microdissection is performed by the pathologist	$-8.10
88381	Microdissection manual	SL085	label for microscope	NF		4	9	9 slides is typical; 9 labels are required	$+0.15

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
			slides						
93312	Echo transesophageal	ED021	computer, desktop, w-monitor	NF		91	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.90
		ED034	video SVHS VCR (medical grade)	NF		43	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.21
		ED036	video printer, color (Sony medical grade)	NF		57	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.61
		EF027	table, instrument, mobile	NF		105	92	Standard equipment and time for moderate sedation	$-0.02
		EL016	room, ultrasound, vascular	NF		57	43	Refined equipment time to conform to established policies for highly technical equipment.	$-24.75
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		105	92	Standard equipment and time for moderate sedation	$-0.18
		EQ032	IV infusion pump	NF		0	92	Standard equipment and time for moderate sedation	$0.58
		L037D	RN/LPN/MTA	NF	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	3	1	Standard times for clinical labor tasks associated with digital imaging	$-0.74

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L050A	Cardiac Sonographer	NF	Clean scope	0	10	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	$5.00
		L050A	Cardiac Sonographer	NF	Clean surgical instrument package	10	0	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	$-5.00
		L050A	Cardiac Sonographer	NF	Process data: measure, record, preliminary findings	8	0	Standard times for clinical labor tasks associated with digital imaging	$-4.00
		L050A	Cardiac Sonographer	NF	Review images with MD	0	2	Standard times for clinical labor tasks associated with digital imaging	$1.00
		L050A	Cardiac Sonographer	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	$-1.50
		SB026	gown, patient	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.53
		SB036	paper, exam table	NF		7	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.10
		SB037	pillow case	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.31
93314	Echo transesophageal	ED021	computer, desktop, w-monitor	NF		61	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.60

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		ED034	video SVHS VCR (medical grade)	NF		53	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.26
		ED036	video printer, color (Sony medical grade)	NF		67	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.71
		EF027	table, instrument, mobile	NF		115	92	Standard equipment and time for moderate sedation	$-0.03
		EL016	room, ultrasound, vascular	NF		67	43	Refined equipment time to conform to changes in clinical labor time; See preamble.	$-42.42
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		115	92	Standard equipment and time for moderate sedation	$-0.32
		EQ032	IV infusion pump	NF		0	92	Standard equipment and time for moderate sedation	$0.58
		L037D	RN/LPN/MTA	NF	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	3	1	Standard times for clinical labor tasks associated with digital imaging	$-0.74
		L050A	Cardiac Sonographer	NF	Assist physician in performing procedure (acquire ultrasound data)	40	30	CPT code 93314 is a less involved service than CPT code 93312, clinical labor time would not be higher. See preamble.	$-5.00

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L050A	Cardiac Sonographer	NF	Clean scope	0	10	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	$5.00
		L050A	Cardiac Sonographer	NF	Clean surgical instrument package	10	0	Time for cleaning probes moved from activity "clean surgical instrument package" to "clean scope". 10 minutes unchanged	$-5.00
		L050A	Cardiac Sonographer	NF	Process data: measure, record, preliminary findings	8	0	Standard times for clinical labor tasks associated with digital imaging	$-4.00
		L050A	Cardiac Sonographer	NF	Review images with MD	0	2	Standard times for clinical labor tasks associated with digital imaging	$1.00
		L050A	Cardiac Sonographer	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	$-1.50
		L051A	RN	NF	Assist physician/moderate sedation (% of physician time)	40	30	CPT code 93314 is a less involved service than CPT code 93312, clinical labor time would not be higher. See preamble.	$-5.10
		SB026	gown, patient	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.53
		SB036	paper, exam table	NF		7	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.10

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		SB037	pillow case	NF		1	0	Duplicative; items are included in pack, minimum multi-specialty visit (SA048)	$-0.31
93320	Doppler echo exam heart	ED021	computer, desktop, w-monitor	NF		5	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.05
93321	Doppler echo exam heart	ED021	computer, desktop, w-monitor	NF		2	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.02
93325	Doppler color flow add-on	ED021	computer, desktop, w-monitor	NF		2	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.02
93702	Bis xtracell fluid analysis	L037D	RN/LPN/MTA	NF	Results are uploaded from the device into the analysis software and a report is generated and printed for physician review.	2	0	Included as an automatic process for the new device.	$-0.74
93880	Extracranial bilat study	ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	$-3.24
93882	Extracranial uni/ltd study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	5	2	Standard times for clinical labor tasks associated with digital imaging	$-1.62
93886	Intracranial complete study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	8	2	Standard times for clinical labor tasks associated with digital imaging	$-3.24
93888	Intracranial limited study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
		L054A	Vascular Technologist	NF	Technologist QCs images in PACS, checking all images, reformats, and dose page	4	2	Standard times for clinical labor tasks associated with digital imaging	$-1.08
93925	Lower extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	$-3.24
93926	Lower extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	5	2	Standard times for clinical labor tasks associated with digital imaging	$-1.62
93930	Upper extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
93931	Upper extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
93970	Extremity study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
93971	Extremity study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
93975	Vascular study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	8	2	Standard times for clinical labor tasks associated with digital imaging	$-3.24
93976	Vascular study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	Technologist reviews & optimizes all duplex images; reviews & optimizes spectrum analysis measuring velocities & assuring proper angle acquisition. Compiles findings with sufficient data for physician review & diagnosis.	5	2	Standard times for clinical labor tasks associated with digital imaging	$-1.62
93978	Vascular study	ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED021	computer, desktop, w-monitor	NF		7	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.07
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
93979	Vascular study	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		10	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.11

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
93990	Doppler flow testing	ED021	computer, desktop, w-monitor	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		ED036	video printer, color (Sony medical grade)	NF		4	0	Duplicative; item is in vascular ultrasound room (EL016)	$-0.04
		L054A	Vascular Technologist	NF	QA Documentation	4	0	Included in overall clinical labor time; see preamble text	$-2.16
95971	Analyze neurostim simple	EF023	table, exam	NF		27	33	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	$0.02
		EQ209	programmer, neurostimulator (w-printer)	NF		27	33	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	$0.04
95972	Analyze neurostim complex	EF023	table, exam	NF		30	36	Include 100% of intraservice time for equipment even when clinical labor assist time is 66% of physician time.	$0.02
		EQ209	programmer, neurostimulator (w-printer)	NF		30	36	Include 100% of intraservice time for equipment even when clinical labor time is 66% of assist physician time.	$0.04
96127	Brief emotional/behav assmt	L026A	Medical/Technical Assistant	NF	Scoring completed behavior assessment tool	15	7	Instructions suggest that it typically takes 7 minutes for scoring the tests included as standardized tests for this procedure.	$-2.08
97605	Neg press wound tx </=50	EF014	light, surgical	NF		28	25	Refined equipment time to conform to changes in clinical	$-0.03

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
	cm							labor time.	
		EF031	table, power	NF		28	25	Refined equipment time to conform to changes in clinical labor time.	$-0.05
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	$-1.11
97606	Neg press wound tx >50 cm	EF014	light, surgical	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	$-0.03
		EF031	table, power	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	$-0.05
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	$-1.11
		EF031	table, power	NF		38	35	Refined equipment time to conform to changes in clinical labor time.	$-0.05
		L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	Intraservice clinical labor time also includes time for wound checking	$-1.11

HCPCS Code	HCPCS Code Description	Input Code	Input Code Description	NF/F/ PO	Labor Activity (where applicable)	RUC Recommend-ation or current value (min or qty)	CMS Refine-ment (min or qty)	Comment	Direct Costs Change
99490	Chron care mgmt srvc 20 min Chron care mgmt srvc 20 min	L051A	RN	NF	Care management activities performed by clinical staff	60	0	20 minutes RN/LPN/MTA time reflects the typical service; see CCM preamble.	$-30.60
		L037D	RN/LPN/MTA	NF	Care management activities performed by clinical staff	0	20	20 minutes RN/LPN/MTA time reflects the typical service; see CCM preamble.	$7.40

iii. Procedures Subject to the Cap on Imaging Codes Defined by Section 5102(b) of the DRA

We are proposing to add the new codes to the list of procedures subject to the DRA cap, effective January 1, 2015. The codes are: (76641 (Ultrasound breast complete), 76642 (Ultrasound breast limited), 77085 (Dxa bone density study), 77086 (Fracture assessment via dxa), 77387 (Guidance for radiaj tx dlvr), G6001 (Stereoscopic x-ray guidance), and G6002 (Echo guidance radiotherapy). These codes, which are new for CY 2015, replace codes deleted for CY 2015 that were subject to the cap, and meet the definition of imaging under section 5102(b) of the DRA. These codes are being added on an interim final basis and are open to public comment in this final rule with comment period.

d. Establishing CY 2015 Interim Final Malpractice RVUs

According to our malpractice methodology discussed in section II.C, we are assigning malpractice RVUs for CY 2015 new, revised, and potentially misvalued codes by utilizing a crosswalk to a source code with a similar malpractice risk. We have reviewed the RUC recommended malpractice source code crosswalks for CY 2015 new, revised, and potentially misvalued codes, and we are accepting all of them on an interim final basis for CY 2015. For G-codes that we are creating, we are also assigning source code crosswalks to similar codes.

Table 32 lists the CY 2015 HCPCS codes and their respective source codes used to set the interim final CY 2015 MP RVUs. The MP RVUs for these services are reflected in Addendum B of this CY 2015 PFS final rule with comment period.

TABLE 32: Crosswalk for Establishing CY 2015 New/Revised/Potentially Misvalued Codes Malpractice RVUs

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
20604	Drain/inj joint/bursa w/us	20600	Drain/inject joint/bursa
20606	Drain/inj joint/bursa w/us	20605	Drain/inject joint/bursa
20611	Drain/inj joint/bursa w/us	20610	Drain/inject joint/bursa
20983	Ablate bone tumor(s) perq	20982	Ablate bone tumor(s) perq
21811	Optx of rib fx w/fixj scope	21805	Treatment of rib fracture

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
21812	Treatment of rib fracture	21805	Treatment of rib fracture
21813	Treatment of rib fracture	21805	Treatment of rib fracture
22510	Perq cervicothoracic inject	22520	Percut vertebroplasty thor
22511	Perq lumbosacral injection	22521	Percut vertebroplasty lumb
22512	Vertebroplasty addl inject	22522	Percut vertebroplasty addl
22513	Perq vertebral augmentation	22523	Percut kyphoplasty thor
22514	Perq vertebral augmentation	22524	Percut kyphoplasty lumbar
22515	Perq vertebral augmentation	22525	Percut kyphoplasty add-on
22858	Second level cer diskectomy	22856	Cerv artific diskectomy
27279	Arthrodesis sacroiliac joint	62287	Percutaneous diskectomy
33270	Ins/rep subq defibrillator	33249	Nsert pace-defib w/lead
33271	Insj subq impltbl dfb elctrd	33216	Insert 1 electrode pm-defib
33272	Rmvl of subq defibrillator	33244	Remove eltrd transven
33273	Repos prev impltbl subq dfb	33215	Reposition pacing-defib lead
33418	Repair tcat mitral valve	92987	Revision of mitral valve
33419	Repair tcat mitral valve	92987	Revision of mitral valve
33946	Ecmo/ecls initiation venous	33960	External circulation assist
33947	Ecmo/ecls initiation artery	33960	External circulation assist
33948	Ecmo/ecls daily mgmt-venous	33961	External circulation assist
33949	Ecmo/ecls daily mgmt artery	33961	External circulation assist
33951	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33952	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33953	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33954	Ecmo/ecls insj prph cannula	36822	Insertion of cannula(s)
33955	Ecmo/ecls insj ctr cannula	33981	Replace vad pump ext
33956	Ecmo/ecls insj ctr cannula	33981	Replace vad pump ext
33957	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33958	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33959	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33962	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33963	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33964	Ecmo/ecls repos perph cnula	33981	Replace vad pump ext
33965	Ecmo/ecls rmvl perph cannula	33981	Replace vad pump ext
33966	Ecmo/ecls rmvl prph cannula	33981	Replace vad pump ext
33969	Ecmo/ecls rmvl perph cannula	33971	Aortic circulation assist
33984	Ecmo/ecls rmvl prph cannula	33971	Aortic circulation assist
33985	Ecmo/ecls rmvl ctr cannula	33977	Remove ventricular device
33986	Ecmo/ecls rmvl ctr cannula	33977	Remove ventricular device
33987	Artery expos/graft artery	33530	Coronary artery bypass/reop
33988	Insertion of left heart vent	33530	Coronary artery bypass/reop
33989	Removal of left heart vent	33257	Ablate atria lmtd add-on
37218	Stent placemt ante carotid	37217	Stent placemt retro carotid
43180	Esophagoscopy rigid trnso	43130	Removal of esophagus pouch
44381	Small bowel endoscopy br/wa	45340	Sig w/balloon dilation
44384	Small bowel endoscopy	44383	Ileoscopy w/stent
45346	Sigmoidoscopy w/ablation	45339	Sigmoidoscopy w/ablate tumr
45347	Sigmoidoscopy w/plcmt stent	45345	Sigmoidoscopy w/stent
45349	Sigmoidoscopy w/resection	43236	Uppr gi scope w/submuc inj

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
45350	Sgmdsc w/band ligation	45332	Sigmoidoscopy w/fb removal
45388	Colonoscopy w/ablation	45383	Lesion removal colonoscopy
45389	Colonoscopy w/stent plcmt	45387	Colonoscopy w/stent
45390	Colonoscopy w/resection	45385	Lesion removal colonoscopy
45393	Colonoscopy w/decompression	45379	Colonoscopy w/fb removal
45398	Colonoscopy w/band ligation	45379	Colonoscopy w/fb removal
47383	Perq abltj lvr cryoablation	47382	Percut ablate liver rf
52441	Cystourethro w/implant	52282	Cystoscopy implant stent
52442	Cystourethro w/addl implant	52282	Cystoscopy implant stent
62302	Myelography lumbar injection	62284	Injection for myelogram
62303	Myelography lumbar injection	62284	Injection for myelogram
62304	Myelography lumbar injection	62284	Injection for myelogram
62305	Myelography lumbar injection	62284	Injection for myelogram
64486	Tap block unil by injection	64447	N block inj fem single
64487	Tap block uni by infusion	64448	N block inj fem cont inf
64488	Tap block bi injection	64447	N block inj fem single
64489	Tap block bi by infusion	64448	N block inj fem cont inf
66179	Aqueous shunt eye w/o graft	66180	Implant eye shunt
66184	Revision of aqueous shunt	66185	Revise eye shunt
76641	Ultrasound breast complete	76645	Us exam breast(s)
76642	Ultrasound breast limited	76645	Us exam breast(s)
77063	Breast tomosynthesis bi	77057	Mammogram screening
77085	Dxa bone density study	77080	Dxa bone density axial
77086	Fracture assessment via dxa	77082	Dxa bone density vert fx
77306	Telethx isodose plan simple	77305	Teletx isodose plan simple
77307	Telethx isodose plan cplx	77315	Teletx isodose plan complex
77316	Brachytx isodose plan simple	77326	Brachytx isodose calc simp
77317	Brachytx isodose intermed	77327	Brachytx isodose calc interm
77318	Brachytx isodose complex	77328	Brachytx isodose plan compl
88341	Immunohisto antibody slide	88342	Immunohisto antibody slide
88344	Immunohisto antibody slide	88342	Immunohisto antibody slide
88364	Insitu hybridization (fish)	88365	Insitu hybridization (fish)
88366	Insitu hybridization (fish)	88365	Insitu hybridization (fish)
88369	M/phmtrc alysishquant/semiq	88368	Insitu hybridization manual
88373	M/phmtrc alys ishquant/semiq	88367	Insitu hybridization auto
88374	M/phmtrc alys ishquant/semiq	88367	Insitu hybridization auto
88377	M/phmtrc alys ishquant/semiq	88368	Insitu hybridization manual
91200	Liver elastography	91132	Electrogastrography
92145	Corneal hysteresis deter	76514	Echo exam of eye thickness
93260	Prgrmg dev eval impltbl sys	93282	Icd device progr eval 1 sngl
93261	Interrogate subq defib	93289	Icd device interrogate
93355	Echo transesophageal (tee)	93312	Echo transesophageal
93644	Electrophysiology evaluation	93642	Electrophysiology evaluation
93702	Bis xtracell fluid analysis	93701	Bioimpedance cv analysis
93895	Carotid intima atheroma eval	93882	Extracranial uni/ltd study
96127	Brief emotional/behav assmt	96110	Developmental screen
99184	Hypothermia ill neonate	99291	Critical care first hour
99490	Chron care mgmt srvc 20 min	99212	Office/outpatient visit est

CY 2015 New, Revised or Misvalued Code		Malpractice Risk Factor Crosswalk Code	
G0277	Hbot, full body chamber, 30m	99183	Hyperbaric oxygen therapy
G0279	tomosynthesis, mamo scre	77055	Mammogram one breast
G0473	Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes	G0477	Behavior counsel obesity 15m

H. Chronic Care Management (CCM)

As we discussed in the CY 2013 PFS final rule with comment period, 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 payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule,'' which appeared in the November 2, 2011 **Federal Register** (76 FR 67802)).
- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Centers for Medicare and Medicaid Innovation's (Innovation Center's) website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/index.html).
- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's website at http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/).
- The Primary Care Incentive Payment (PCIP) Program (described on the CMS website at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available

(described on the CMS website at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf).

- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS website at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/FQHC_APCP_Demo_FAQsOct2011.pdf and the Innovation Center's website at www.innovations.cms.gov/initiatives/FQHCs/index.html).
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's website at http://innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In addition, HHS leads a broad initiative focused on optimizing health and quality of life for individuals with multiple chronic conditions. HHS's Strategic Framework on Multiple Chronic Conditions outlines specific objectives and strategies for HHS and private sector partners centered on strengthening the health care and public health systems; empowering the individual to use self-care management with the assistance of a healthcare provider who can assess the patient's health literacy level; equipping care providers with tools, information, and other interventions; and supporting targeted research about individuals with multiple chronic conditions and effective interventions. Further information on this initiative is available on the HHS website at http://www.hhs.gov/ash/initiatives/mcc/index.html.

In coordination with all of these initiatives, 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. For example, in

the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital 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 to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic conditions beginning in CY 2015 (78 FR 74414).

1. Valuation of CCM Services – GXXX1

CCM is a unique PFS service designed to pay separately for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions. (See 78 FR 74414 for a more thorough discussion of the beneficiaries for whom this service may be billed and the scope of service elements.) In the CY 2014 PFS final rule with comment period, we indicated that, to recognize the additional resources required to furnish CCM services to patients with multiple chronic conditions, we were creating the following code to use for reporting this service (78 FR 74422):

- GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days.

Although this service is unique in that it was created to separately pay for care management services, other codes include care management components. To value CCM, we compared it to other codes that involve care management. In doing so, we concluded that the CCM services were similar in work (time and intensity) to that of the non-face-to-face portion of

the lower level code for transitional care management (TCM) services (CPT code 99495 (Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge)). Accordingly, we based the proposed inputs on the non-face-to-face portion of CPT code 99495.

Specifically, we proposed a work RVU for GXXX1 of 0.61, which is the portion of the work RVU for CPT code 99495 that remains after subtracting the work attributable to the face-to-face visit. (CPT code 99214 (Office/outpatient visit est) was used to value CPT code 99495, which has a work RVU of 1.50). Similarly, we proposed a work time of 15 minutes for HCPCS code GXXX1 for CY 2015 based on the time attributable to the non-face-to-face portion of CPT 99495.

For direct PE inputs, we proposed 20 minutes of clinical labor time. As established in the CY 2014 PFS final rule with comment period, in order to bill for this code, at least 20 minutes of CCM services must be furnished during the 30-day billing interval (78 FR 74422). Based upon input from stakeholders and the nature of care management services, we believed that many aspects of this service will be provided by clinical staff, and thus, clinical staff would be involved in the typical service for the full 20 minutes. CPT code 99495 has 45 minutes of non-face-to-face clinical labor time and we assumed the typical case for CCM would involve 20 minutes based upon the code descriptor and a broad eligible population that would require limited monthly services. The proposed CY 2015 direct PE input database reflected the input of 20 minutes of clinical labor time and is available on the CMS website under the supporting data files for the CY 2015 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-

Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The resulting proposed PE RVUs were 0.57 for CCM furnished in non-facility locations and 0.26 for CCM furnished in a facility.

The proposed MP RVU of 0.04 was calculated using the weighted risk factors for the specialties that we believed would furnish this service. We believed the proposed malpractice risk factor would appropriately reflect the relative malpractice risk associated with furnishing CCM services.

We received many public comments on our proposed valuation. In general, the commenters commended CMS for ongoing recognition of the value of non-face-to-face time expended by physicians and staff to improve outcomes for beneficiaries with chronic conditions, and the proposal to pay separately for the non-face-to-face services. However, the commenters generally believed the proposed valuation for CCM services underestimated the resources involved with complex beneficiaries, and recommended various alternatives for valuing the services. We summarize these comments in the following paragraphs.

Comment: Several commenters noted that the CPT Editorial Panel created a new code for CY 2015 that is extremely similar to the G-code we developed to report these services. These commenters suggested that we use the new 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).

Many of these commenters expressed a preference for the "per calendar month" used in the CPT descriptor to the "per 30 days" used in the G-code. The commenters said a calendar month rather than 30 days would be less complex administratively.

Response: It is our preference to use CPT codes unless Medicare has a programmatic need that is not met by the CPT coding structure. Accordingly, in the CY 2014 final rule with comment period we indicated that we would consider using a CPT code if one was created that reflected the service we were describing with the G-code. We believe that the new CPT code 99490 appropriately describes CCM services for Medicare beneficiaries.

We had used 30 days rather than a calendar month as the service period for the G-code so that the number of days in the service period would not vary based upon when CCM services were initiated for a given period. For example, if the services were initiated near the end of a calendar month, using the CPT code's period of "per calendar month" would make it harder for the practitioner to meet the required minimum time for the month and be able to bill CMM for that month.

However, after learning about the administrative difficulties that the 30-day period would create, we believe that the calendar month creates a reasonable period. Accordingly, we will adopt CPT code 99490 for Medicare CCM services, effective January 1, 2015 instead of the G code.

Comment: Several commenters suggested alternative approaches to the use of codes that describe CCM services. For example, one commenter said that the code should be for one year, with average of 20 minutes per month across the year. Another commenter was concerned about how the 20 minutes of care per month per patient will be calculated, because some patients

(those whose condition is less well controlled) will demand more attention and care than average patients, while those whose condition is well controlled might require very little attention. This commenter suggested that a reasonable solution would be for the care minutes per patient per month to be calculated as an average across a number of CCM patients. The commenter added that for patients entering and exiting mid-month, the average minutes of care could be calculated on a pro rata basis which adjusts for the partial months they are eligible for CCM services. Several other commenters said that CMS should use a capitated payment methodology for CCM services in the long run, but supported CCM services using the CPT codes as valued by the RUC as a short-term transitional strategy until CMS is able to expand the per beneficiary per month care management fee under CMS's primary care demonstration initiatives to all physicians. Others commented similarly that the long-term goal is capitated payments like the demonstrations/models that better encourage population-based health management and reducing utilization.

Several commenters submitted recommendations for valuation based on their experience in CMS's Patient-Centered Medical Home multipayer initiative. Assuming CCM services are furnished by a care manager receiving an annual salary of $150,000, and taking into account a commonly accepted patient to care manager ratio of 1:150, these commenters believed that under the proposed payment rate, the average service time possible would be a ceiling of 23 minutes (not a floor of 20 minutes). Based on one tracking study of care manager activity in minutes per patient per month, they believed complex care management would require 42 minutes of face-to-face and non-face-to-face time per month. Assuming the same care manger salary and patient load, the commenters asserted that the monthly payment amount necessary to provide this amount of care would be $83 per beneficiary per month.

Response: Our proposal to pay separately for these services is part of a broader series of potential refinements to the PFS that appropriately value care management within Medicare's statutory structure for fee-for-service physician payment. We do not have statutory authority to base payment under the PFS on a recurring per beneficiary per month basis. The PFS is limited to a fee-for-service model at present, and as such we do not use capitated payment for services that may or may not be furnished in a given month. We refer the commenter and other interested stakeholders to the preceding paragraphs that describe a broader set of initiatives that are designed to improve payment for, and encourage long-term investment in, care management services, including a variety of CMS and HHS programs and demonstrations.

Comment: Many commenters recommended a higher valuation for CCM services than was proposed, with some commenters providing specific suggestions as to changes in inputs and others simply asserting that a higher payment was appropriate or necessary to achieve access or the desired benefit. One commenter recommended a payment of $75 but did not provide supporting information. Several other commenters recommended that CMS adopt the RUC-recommended values for CPT code 99490 (work time of 30 minutes, work RVU of 1.0, and 60 minutes of clinical labor time). Several commenters believed CMS should adopt the work, PE and MP RVUs for CPT code 99495, with one commenter suggesting that CMS crosswalk the PE and MP RVU from the TCM code and not just the work RVU from the code in order to equalize payment for the CCM code with a per beneficiary per month payment that is made for similar services through a state Medicaid program. Another commenter pointed out that the proposed combined MP and PE RVU of 0.61 for CCM is significantly lower than for the following similar services that cannot be billed during same period with CCM: HCPCS code G0181 (Home Healthcare Oversight) which has a combined MP and PE RVU of 1.28; HCPCS code G0182

(Hospice Care Plan Oversight) which has a combined MP and PE RVU of 1.30; CPT code 99339 (Care Plan Oversight Services) which has a combined MP and PE RVU of 0.94; and CPT code 99358 (Prolonged Services without Direct Patient Contact) which has a combined MP and PE RVU of 0.98.

Several commenters suggested that CMS's comparison with TCM, CPT code 99495, was not an appropriate comparison. One commenter asked what codes other than CPT code 99495 CMS considered as similar to CCM for purposes of CCM valuation. This commenter believed the time and intensity required for the non-face-to-face portion of CPT code 99495 is not the same as for CCM services.

Several commenters suggested that CMS should develop PE RVUs for the service using alternative methodologies than for other PFS services. For example, several commenters stated that CMS should adjust the PE RVUs to account for major infrastructure and other costs required for CCM, especially health information technology, computer equipment, 24/7 beneficiary access, extensive documentation, nursing staff and other overhead costs. One commenter believed the proposed RVUs accounted for personnel costs but not the practice expense for health information technology, workforce retooling, and analytics.

We received many public comments on the appropriate work time and direct PE inputs for clinical staff time. Most suggested that the proposed inputs for time were too low and recommended using the RUC-recommended values (work time of 30 minutes and 60 minutes of clinical labor time). Regarding clinical labor time, some commenters believed the proposed 20 minutes of clinical labor was too low, being the 25th percentile for work time in the RUC survey, and they noted the significantly higher time reported in response to the RUC survey of 60 minutes of clinical labor time. Another commenter said that assuming 20 minutes of service

time per month as typical significantly undervalues the service and questioned how CMS arrived at that number. Regarding the work time, several commenters addressed the work RVU, recommending that the proposed RVU be adjusted upwards but did not specify by how much. Several commenters noted that the RUC recommendation of 1.0 work RVU for CPT codes 99490 and 99487 (Cmplx chron care w/o pt visit) is based on median survey work times of 30 minutes and 26 minutes, respectively, for these CCM codes. (The long descriptor for CPT code 99487 is, 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).

However several commenters did not object to the proposed valuation for GXXX1 and recommended that CMS monitor payment adequacy and appropriate valuation once the code is implemented.

Response: After consideration of the various comments on the work RVUs, we continue to believe that the most appropriate mechanism for determining the appropriate work RVU for this service is by using the non-face-to-face portion of the lower level TCM code, CPT code 99495. We continue to believe that the work and intensity for CCM services furnished to the eligible beneficiaries is comparable to the work and intensity involved in furnishing the non-

face-to-face portion of the service described by CPT code 99495. Therefore, we believe that using CPT code 99495 as the comparison code assures appropriate relativity with other similar services. The services suggested by the commenters as comparable to the CCM code require significantly more time. CPT code 99358 is for an hour of non-face-to-face time and has a work time of 60 minutes. CPT code 99339 has a work time of 40 minutes and is furnished to a significantly different patient population (those in a domiciliary or rest home). HCPCS codes G0181 and G0182 have work time of almost 60 minutes and also are furnished to significantly different patient populations.

We appreciate commenters' concerns regarding the various kinds of practice expense and malpractice liability costs that practices incur as they manage beneficiaries requiring CCM services. However, we continue to believe that our established PE and MP methodology used to value the wide ranges of services across the PFS assures that we have the appropriate relativity in our payments.

Although many commenters recommended that we use the time from the RUC survey of 60 minutes of clinical labor and 30 minutes of work time, we believe that since CCM is a new separately billable service, the survey data may be less reliable as the practitioners would have no experience with the code. Since at least 20 minutes of services are required to be furnished in order to report the service and our information, including comments, suggests that many beneficiaries who meet Medicare's criteria for CCM services would not need more than the minimum required minutes of service, we believe 60 minutes would overestimate the typical number of clinical labor minutes during one month for the typical eligible beneficiary. Accordingly, we are finalizing our proposed work and clinical labor times.

Comment: A number of commenters recommended that coinsurance should not apply to

CCM services. These commenters were concerned that the $8 estimated coinsurance amount in the proposed rule would hinder beneficiary access. Several commenters believed that CCM is a preventive service that should be exempt from beneficiary cost sharing. They noted that cost-sharing will make it challenging to reach the 20 minutes required for billing, because beneficiaries will delay care until face-to-face is necessary

Response: CCM services do not fall into any of the statutory preventive services benefit categories of the Act. The Secretary has the authority to add "additional preventive services" that, among other things, have been assigned an "A" or "B" rating by the United States Preventive Services Task Force, but CCM has not earned such a rating. Since CCM does not meet the criteria, we cannot designate it as an additional preventive service under section 1861(s)(2)(BB) of the Act. Further, we do not have other statutory authority that would allow us to waive the applicable coinsurance for CCM services. As discussed in the CY 2014 PFS final rule with comment period (78 FR 74424), in order to assure that beneficiaries are aware of the coinsurance for this non-face-to-face service, we are requiring that providers explain to beneficiaries the cost-sharing obligation involved in receiving CCM services and obtain their consent prior to furnishing the service. Practitioners should explain that a likely benefit of agreeing to receive CCM services is that although cost-sharing applies to these services, CCM services may help them avoid the need for more costly face to face services that entail greater cost-sharing.

Comment: Most of the commenters were concerned that the proposed payment would not be adequate for beneficiaries with complex needs who would benefit the most from CCM services. Most of the commenters recommended that we adopt more than one code to provide differential payment for more and less complex beneficiaries, using CPT CCM codes, G-code(s)

or some combination thereof. Many commenters distinguished between beneficiaries that require significantly different clinical resources--those needing "complex chronic care management" and those needing only "standard chronic care or disease management." Some commenters asserted that there is a disconnect between the code descriptor for GXXX1 and the Medicare CCM scope of service, such that ambiguity in the descriptor will result in use of GXXX1 to treat a very broad spectrum of beneficiaries inconsistent with the scope of service that the commenters believed was consistent with beneficiaries with more complex needs. They believed the proposed payment amount is appropriate for beneficiaries on needing only standard chronic care management, but would significantly underpay for beneficiaries requiring complex chronic care management.

Many commenters recommended that CMS adopt the three CPT codes describing chronic care management. In addition to the CPT code that is similar to the G-code described above (CPT code 99490), there are two additional complex chronic care coordination codes (a base code and an add-on code). Since CY 2013 when the complex chronic care coordination codes became available, CMS has bundled these codes. The base code is CPT code 99487 (Cmplx chron care w/o pt visit), and the add-on is CPT code 99489 (Complex chronic care coordination services; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (list separately in addition to code for primary procedure).

Other commenters recommended using two codes to describe CCM for different patient populations, or a base code and an add-on code to describe CCM for a single patient population. Some commenters recommended adoption of GXXX1 or CPT code 99490, plus CPT code 99487 along with the RUC-recommended values, to describe CCM for the two distinct populations that

require different services. These commenters stated that there is no "typical" patient that characterizes both groups of patients, and that a large number of eligible beneficiaries (those having 2 or more chronic conditions) have serious mental health and/or substance abuse disorders and would benefit greatly from CCM services). Other commenters recommended using two G-codes, one being an add-on code for each additional 20 minutes or other time spent caring for a beneficiary with more complex needs. One commenter urged CMS to adopt an add-on code for time increments over 60 minutes. Several commenters recommended a cap on additional minutes, particularly if CMS finalizes an applicable beneficiary coinsurance for CCM services. One commenter recommended that we finalize the proposed valuation for GXXX1, also recognize CPT code 99490 (Chron care mgmt srvc 20 min) with a higher payment amount, and then collect data on the impacts of differential payment amounts.

Other commenters recommended that CMS adopt CPT code 99487 (Cmplx chron care w/o pt visit) with the scope of services for GXXX1. One commenter recommended that CMS redefine its requirements and the scope of services for GXXX1 to be more consistent with chronic disease management, using CPT code 99487. The commenter believed we should adopt CPT code 99487 with the RUC-recommended valuation. One commenter more generally recommended that CMS adopt a higher intensity code for patients requiring 45-60 minutes or more of clinical staff time for assessment, medication management, care planning, coordination, education and advocacy.

Response: At this time, we believe that Medicare beneficiaries with two or more chronic conditions as defined under the CCM code can benefit from care management and want to make this service available to all such beneficiaries. Like all services, we recognize that some beneficiaries will need more services and some less, and thus we pay based upon the typical

service. However all scope of service elements apply for delivery of CCM services to any eligible Medicare beneficiary. We will evaluate the utilization of this service to evaluate what types of beneficiaries receive the service described by this CPT code, what types of practitioners are reporting it, and consider any changes in payment that may be warranted in the coming years. We are maintaining the status indicator "B" (Bundled) for CY 2015 for the complex care coordination codes, CPT codes 99487 and 99489.

Comment: Several commenters requested that CMS create codes specific to remote patient biometric monitoring (recording vital signs and other physiological data and transmitting real-time data to physicians). Several commenters requested codes specific to or inclusive of certain hematology, nephrology, endocrine and allergy/immunology conditions, such as chronic kidney disease, end-stage renal disease, diabetes and severe asthma. One commenter recommended that CMS delay implementation of this service for CY 2015 and propose for CY 2016 specific complex chronic care codes for each of the major chronic diseases, especially diabetes.

Response: We are not convinced that the care management services are sufficiently unique based upon the beneficiary's specific chronic conditions to warrant separate codes, especially given the beneficiary must have at least two chronic conditions. As noted above, we will be monitoring this service and will consider making changes if they appear warranted.

After consideration of the comments received on this proposal, we are finalizing the proposal with the following modification. Rather than creating a G-code we are adopting the new CPT code, 99490, to describe CCM services effective January 1, 2015. We intend to evaluate this service closely to assess whether the service is targeted to the right population and whether the payment is appropriate for the services being furnished. As part of our evaluation,

we will consider the whether this new service meets the care coordination needs of Medicare beneficiaries and if not how best to address the unmet needs.

2. CCM and TCM Services Furnished Incident to a Physician's Service under General Physician Supervision

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we discussed how the policies relating to services furnished incident to a practitioner's professional services apply to CCM services. (In this discussion, the term practitioner means both physicians and NPPs who are permitted to bill for services furnished incident to their own professional services.) Specifically, we addressed the policy for counting clinical staff time for services furnished incident to the billing practitioner's services toward the minimum amount of service time required to bill for CCM services.

We established an exception to the usual rules that apply to services furnished incident to the services of a billing practitioner. Generally, under the "incident to" rules, practitioners may bill for services furnished incident to their own services if the services meet the requirements specified in our regulations at §410.26. One of these requirements is that the "incident to" services must be furnished under direct supervision, which means that the supervising practitioner must be present in the office suite and be immediately available to provide assistance and direction throughout the service (but does not mean that the supervising practitioner must be present in the room where the service is furnished). We noted in last year's PFS final rule with comment period that, because one of the required elements of the CCM service is beneficiary access to the practice 24-hours-a-day, 7-days-a-week, to address the beneficiary's chronic care needs (78 FR 74426), we expect the beneficiary to be provided with a means to make timely contact with health care providers in the practice whenever necessary to address chronic care

needs regardless of the time of day or day of the week. In those cases when the need for contact arises outside normal business hours, it is likely that the beneficiary's initial contact would be with clinical staff employed by the practice (for example, a nurse) and not necessarily with a practitioner. Under these circumstances, it would be unlikely that a practitioner would be available to provide direct supervision of the service.

Therefore, in the CY 2014 PFS final rule with comment period, we created an exception to the generally applicable requirement that "incident to" services must be furnished under direct supervision. Specifically, we finalized a policy to require only general, rather than direct, supervision when CCM services are furnished incident to a practitioner's services outside of the practice's normal business hours by clinical staff who are direct employees of the practitioner or practice. We explained that, given the potential risk to beneficiaries that the exception to direct supervision could create, we believed that it was appropriate to design the exception as narrowly as possible (78 FR 74426). The direct employment requirement was intended to balance the less stringent general supervision requirement by ensuring that there is a direct oversight relationship between the supervising practitioner and the clinical staff personnel who provide after-hours services.

In the CY 2015 PFS proposed rule, we proposed to revise the policy that we adopted in the CY 2014 PFS final rule with comment period. We also proposed to amend our regulations to codify the requirements for CCM and TCM services furnished incident to a practitioner's services. Specifically, we proposed to remove the requirement that, in order to count the time spent by clinical staff providing aspects of CCM services toward the CCM time requirement, the clinical staff person must be a direct employee of the practitioner or the practitioner's practice. (We note that the existing requirement that these services be provided by clinical staff,

specifically, rather than by other auxiliary personnel is an element of the service for both CCM and TCM services, rather than a requirement imposed by the "incident to" rules themselves.) We also proposed to remove the restriction that services provided by clinical staff under general (rather than direct) supervision may be counted only if they are provided outside of the practice's normal business hours. Under our proposed revised policy, then, the time spent by clinical staff providing aspects of CCM services can be counted toward the CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all other requirements of the "incident to" regulations at §410.26 are met.

We proposed to revise these aspects of the policy for several reasons. First, one of the required elements of the CCM service is the availability of a means for the beneficiary to make contact with health care practitioners in the practice to address a beneficiary's urgent chronic care needs (78 FR 74418 through 74419). Other elements within the scope of CCM services are similarly required to be furnished by practitioners or clinical staff. We believe that these elements of the CCM scope of service require the presence of an organizational infrastructure sufficient to adequately support CCM services, irrespective of the nature of the employment or contractual relationship between the clinical staff and the practitioner or practice. We also believe that the elements of the CCM scope of service, such as the requirement of a care plan, ensure a close relationship between a practitioner furnishing ongoing care for a beneficiary and clinical staff providing aspects of CCM services under general supervision; and that this close working relationship is sufficient to render a requirement of a direct employment relationship or direct supervision unnecessary. Under our proposal, CCM services could be furnished "incident to" if the services are provided by clinical staff under general supervision of a practitioner whether or not they are direct employees of the practitioner or practice that is billing for the

service; but the clinical staff must meet the other requirements for auxiliary personnel including those at §410.26(a)(1). Other than the exception to permit general supervision for clinical staff, the same requirements apply to CCM services furnished incident to a practitioner's professional services as apply to other "incident to" services. Furthermore, since last year's final rule, we have had many consultations with physicians and others about the organizational structures and other factors that contribute to effective provision of CCM services. These consultations have convinced us that, for purposes of clinical staff providing aspects of CCM services, it does not matter whether the practitioner is directly available to supervise because the nature of the services are such that they can be, and frequently are, provided outside of normal business hours or while the physician is away from the office during normal business hours. This is because, unlike most other services to which the "incident to" rules apply, the CCM services are intrinsically non-face-to-face care coordination services.

In conjunction with this proposed revision to the requirements for CCM services provided by clinical staff incident to the services of a practitioner, we also proposed to adopt the same requirements for equivalent purposes in relation to TCM services. As in the case of CCM, TCM explicitly includes separate payment for services that are not necessarily furnished face-to-face, such as coordination with other providers and follow-up with beneficiaries. It would also not be uncommon for auxiliary personnel to provide elements of the TCM services when the physician was not in the office. Generally, we believe that it is appropriate to treat separately billable care coordination services similarly whether in the form of CCM or TCM. We also believe that it would be appropriate to apply the same "incident to" rules that we are proposing for CCM services to TCM services. We did not propose to extend this policy to the required face-to-face portion of TCM. Rather, the required face-to-face portion of the service must still

be furnished under direct supervision.

Therefore, we proposed to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. As with other "incident to" services, 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. We note that all other "incident to" requirements continue to apply and that the usual documentation of services provided must be included in the medical record.

Commenters uniformly supported our proposal to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. Under the revised regulation, then, the time spent by clinical staff providing aspects of TCM and CCM services can be counted toward the TCM or CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all requirements of the revised "incident to" regulations at §410.26 are met.

Comment: One commenter requested guidance concerning whether (as has been the case with E/M codes) activities billed under "incident to" will not be able to also be billed under the CCM code.

Response: The purpose of our proposal was to allow elements of CCM services that are furnished by clinical staff incident to a practitioner's professional services (under the "incident to" regulations) to be included and reported as CCM services. We are not entirely clear what the

commenter is asking, but the time spent furnishing CCM services can only be counted once and for only one purpose, and each discrete service can be billed only once. Although we and our contractors provide many educational materials, practitioners who furnish Medicare covered items and services are responsible for learning how to appropriately bill each service.

Comment: One commenter urged us to revise the terminology by which we define the CCM and TCM services to reflect non-hierarchical interdisciplinary team care, rather than relying on an incident-to structure that obscures the actual provider of direct patient care. This commenter expressed concern about loss of benefits to clinicians under contract with a practice, rather than being employed by the practice. Another commenter similarly expressed concern that the expanded authorization for "general supervision" rather than "direct supervision" would provide an even greater incentive for physicians to require that any E/M service provided by an Advanced Practice Registered Nurse (APRN) in their practice be billed as "incident to" a physician's service. This could reduce transparency in billing data and diminish accountability for services for Part B beneficiaries.

Response: We do not entirely understand the basis for these concerns. We have accommodated numerous requests to include contracted employees within the scope of the "incident to" rules for purposes of counting time toward the TCM and CCM requirements. We have not otherwise proposed to revise the "incident to" and other regulations within which practitioners operate as they make decisions about whether to contract or directly employ clinical staff, or about how to bill for services provided. Although they are important within the context of the new TCM and CCM services, we believe that the revisions to our "incident to" regulation that are adopted in this final rule, are peripheral in the context of the overall employment and billing practices of physicians and group practices.

After consideration of the comments, we are finalizing our proposal to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit the CCM and non-face-to-face portion of the TCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner.

3. Scope of Services and Standards for CCM Services

In the CY 2014 final rule with comment period (78 FR 74414 through 74428), we defined the elements of the scope of service for CCM that are required for a practitioner to bill Medicare for the CCM service. In addition, we indicated that we intended to develop standards for practices that furnish CCM services to ensure that the practitioners who bill for these services have the capability to fully furnish them (78 FR 74415, 74418). At that time, we anticipated that we would propose these standards in the CY 2015 PFS proposed rule. We actively sought input toward development of these standards by soliciting public comments on the CY 2014 PFS final rule with comment period, through outreach to stakeholders in meetings, by convening a Technical Expert Panel, and by collaborating with federal partners such as the Office of the Assistant Secretary for Planning and Evaluation, the Office of the Assistant Secretary for Health, the Office of the National Coordinator for Health Information Technology (ONC), and the Health Resources and Services Administration. Our goal is to recognize the trend toward practice transformation and overall improved quality of care, while preventing unwanted and unnecessary care.

As we worked to develop appropriate practice standards that would meet this goal, we consistently found that many of the standards we thought were important overlapped in significant ways with the scope of service or with the billing requirements for the CCM services

that had been finalized in the CY 2014 final rule with comment period. In cases where the standards we identified were not unique to CCM requirements, we found that the standards overlapped with other Medicare requirements or other federal requirements that apply generally to health care practitioners. Based upon the feedback we received, we sought to avoid duplicating other requirements or, worse, imposing conflicting requirements on practitioners that would furnish CCM services. Given the standards and requirements that are already in place for health care practitioners and applicable to those who furnish and bill for CCM services, we decided not to propose an additional set of standards that would have to be met in order for practitioners to furnish and bill for CCM services. Instead of proposing a new set of standards applicable to only CCM services, we decided to emphasize that certain requirements are inherent in the elements of the existing scope of service for CCM services, and clarify that these must be met in order to bill for CCM services. The CCM scope of service elements finalized in the CY 2014 PFS final rule (78 FR 74414 through 74428) are as follows.

- The provision of 24-hour-a-day, 7-day-a-week access to address the patient's acute chronic care needs. To accomplish this, the patient must be provided with a means to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week.

- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.

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

- In consultation with the patient, any caregiver and other key practitioners treating the patient, the practitioner furnishing CCM services must create a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values. The care plan is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues, and typically includes, but is not 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 billing practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision of the care plan. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care, including referrals to other clinicians, follow-up after the patient's visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities. The practice must facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to the patient in a timely way so as to reduce the need for repeat visits to emergency departments and readmissions to hospitals, skilled nursing facilities or other health care facilities.

- Coordination with home and community based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from

home and community based providers regarding these patient needs must be documented in the patient's medical record.

- Enhanced opportunities for the beneficiary and any relevant caregiver to communicate with the practitioner regarding the beneficiary's care through, not only telephone access, but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

Similarly, we reminded stakeholders of the following additional billing requirements established in the CY 2014 final rule with comment period (in the following list, we have changed the service period from the 2015 proposed 30-day period to the final 2015 service period of one calendar month):

- Inform the beneficiary about the availability of the CCM services from the practitioner and obtain his or her written agreement to have the services provided, including the beneficiary's authorization for the electronic communication of the patient's medical information with other treating providers as part of care coordination.

- Document in the beneficiary's medical record that all elements of the CCM service were explained and offered to the beneficiary, and note the beneficiary's decision to accept or decline the service.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a calendar month) and the effect of a revocation of the agreement to receive CCM services.

- Inform the beneficiary that only one practitioner can furnish and be paid for these services during the calendar month service period.

In one area, electronic health records (EHRs), we were concerned that the existing elements of the CCM service could leave some gaps in assuring that beneficiaries consistently receive care management services that offer the benefits of advanced primary care as it was envisioned when this service was created. It is clear that effective care management can be accomplished only through regular monitoring of the patient's health status, needs, and services, and through frequent communication and exchange of information with the patient and among the various health care practitioners and providers treating the patient. After gathering input from stakeholders through the CY 2014 rulemaking cycle, for 2015 we proposed a new scope of service element that would require use of a certified EHR and electronic care planning to furnish CCM services. We believed that requiring those who furnish CCM services to utilize EHR technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology was necessary to ensure that key patient information is stored, shared and reconciled among the many practitioners and providers involved in managing the patient's chronic conditions, otherwise care could not be coordinated and managed. Requiring a certified EHR would enable members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Therefore we proposed that the billing practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. We proposed that at a minimum, the practice must utilize EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), 170.314(a)(4), 170.314(a)(5),

170.314(a)(6), 170.314(a)(7) and 170.314(e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record. These sections of the regulation comprise the certification criteria for specific core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) for the 2014 edition. Under the proposal, practitioners furnishing CCM services beginning in CY 2015 would be required to utilize an EHR certified to at least these 2014 edition certification criteria. Given these 2014 edition criteria, the EHR technology would be certified to capture data and ultimately produce summary records according to the HL7 Consolidated Clinical Document Architecture standard (see 45 CFR 170.205(a)(3)).

In addition, when any of the CCM scope of service elements refers to a health or medical record, we proposed to require use of an EHR certified to at least the 2014 edition certification criteria to fulfill the scope of service element in relation to the health or medical record. As finalized in the CY 2014 PFS final rule, the scope of service elements that reference a health or medical record are:

- A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
- 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.
- 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.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

Regarding the care plan in particular, we believed that requiring practitioners furnishing CCM services to maintain and share an electronic care plan would alleviate the errors that can occur when care plans are not systematically reconciled. To ensure that practices offering CCM services meet these needs, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all practitioners within the practice, including being accessible to those who are furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. This was a more limited proposal compared to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the beneficiary's full electronic medical record (78 FR 74416 through 74417).

Regarding the clinical summary, we proposed to require technology certified to the 2014 edition for the electronic creation of the clinical summary, formatted according to the standard adopted at 45 CFR 170.205(a)(3), but we did not specify that this format must be used for the exchange of beneficiary information (79 FR 40367). For instance, we did not propose that practitioners billing for CCM services must adopt certified technology related to the exchange of a summary care record such as the transmission standard related to Direct Project Transport in 45 CFR 170.314(b)(2)(ii).

We indicated that we believed our proposed new scope of service element for a certified EHR and electronic care planning would ensure that practitioners billing for CCM could fully furnish the services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. We indicated that we believed that allowing flexibility as to how practitioners capture, update, and share care plan information was important at this stage given the maturity of current EHR standards and other electronic tools in use in the market today for care planning.

In addition to seeking comment on this new proposed scope of service element, we sought comment on any changes to the scope of service or billing requirements for CCM services that may be necessary to ensure that the practitioners who bill for these services have the capability to furnish them and that we can appropriately monitor billing for these services. With the addition of the electronic health information technology element that we proposed, we believed that the elements of the scope of service for CCM services, when combined with other important federal health and safety regulations, would provide sufficient assurance that practitioners billing for CCM could fully furnish the services, and that Medicare beneficiaries receiving CCM would receive appropriate services. However we expressed special interest in receiving public feedback regarding any meaningful elements of the CCM service or beneficiary protections that may be missing from the scope of service elements and billing requirements.

The following paragraphs summarize the comments we received regarding these elements of the scope of service for CCM services and our responses.

Comment: Some commenters were disappointed that CMS did not propose an additional set of standards. The commenters expressed concern that there would not be sufficient accountability for high quality CCM services. Some commenters recommended further

development of standards such as inclusion of evidence-based self-management programs offered by community organizations, quality measures that engage patients and demonstrate improved outcomes, or a best practices guide to assist the physician community with implementation. However, many commenters opposed further standards, and agreed with CMS that additional standards would largely overlap with other Medicare requirements or were already reflected in the scope of service elements.

Response: We appreciate the commenters' concerns about ensuring quality of care. We continue to believe that with the addition of the EHR element, the required scope of service elements are sufficient for ensuring high quality CCM services in 2015. We note that section III.K of this final rule with comment period addresses quality measures for physicians' services, and stakeholders may submit suggestions for quality measures related to CCM in response to this section of the regulation.

Comment: Many commenters expressed broad support for our EHR proposal. The commenters commended the strong emphasis on data sharing and requirements for a robust EHR as vital to successful care coordination and continuity of care. Several commenters did not believe the proposal would pose a significant administrative burden. One commenter noted that use of an EHR would help practitioners to document the time spent furnishing CCM services.

Although commenters supported adoption of certified EHR technology (CEHRT) generally, many were concerned that an insufficient number of physicians have adopted CEHRT with the functionalities we proposed for CCM, especially interoperability with other providers. The commenters were also concerned that physicians practicing in rural or economically depressed areas would not have the resources to implement such technology and would be disqualified from furnishing separately billable CCM services. Many believed the proposal was

laudable but premature, recommending that CMS delay adoption of the 2014 EHR certification criteria for CCM services by 3 to 4 years when they will be more widely adopted, or phase in the 2014 certification criteria over 2 years as a requirement for 2017. Several commenters recommended that we finalize our proposal but provide hardship exceptions for certain smaller or rural practices to enable them to bill separately for CCM services in the absence of an interoperable EHR in certain circumstances, provide financial incentives, or allow other flexibility around the requirements for physicians who cannot meet them at this time. One commenter supported the proposal but suggested we allow aspects of CCM services to be furnished using fax and secure messaging technology if physicians encounter challenges with interoperability. Until EHR systems are interoperable, some commenters suggested allowing practitioners to attest that all requirements for billing CCM were met using CEHRT or an alternative technology, or to attest that all members of the care team have timely access (24/7 access in "real time" or "near real time") to the most updated information regarding the care plan through either electronic or non-electronic means, with ongoing efforts to implement interoperable EHRs. The commenters stated many practices are making patient information accessible in a timely manner to the entire care team, but have not yet fully implemented an interoperable EHR with other providers. Several commenters were concerned about the ability of current EHR technologies to share information across different providers and EHR systems. Commenters requested that CMS ensure that no certified EHR contains technological or business impediments to data sharing across disparate technology platforms used by multiple providers trying to coordinate care. In addition, many commenters were concerned about access to CCM services, and recommended that CMS prioritize access over adoption of CEHRT. Several

commenters stated that not all types of physicians have access to an EHR that meets the needs of their specialty.

A number of commenters stated that CCM could be (and already is) effectively provided without any EHR or a without a certified EHR, and recommended that CMS rescind the proposal or make the EHR requirement optional. These commenters disagreed with the requirement that CCM services must be furnished with use of a certified EHR, information technology (IT) platform or exchange platform that includes a care plan, with some stating that certified EHR systems have not demonstrated improvements in the management of chronic conditions, especially complex cases, and suggested postponing the care plan and other EHR requirements until they are proven effective and adopted by most providers. Others stated that an EHR was necessary and that CMS should require an EHR that promotes communication among various professional on the care team, includes the patient as part of the team, and enables clinical monitoring and effective care planning. Commenters indicated that many physicians accomplish this through generating or receiving electronic discharge summaries, clinical documentation, and patient-centered plans of care, but are not using certified technologies to carry out these functions and should not be penalized.

One commenter stated that only about half of all physicians had an EHR system with advanced functionalities in 2013, many current systems were not designed with interoperability in mind and transition costs are high. The commenter believed the proposed payment amount would not sufficiently cover the cost of purchasing or upgrading an EHR system, and requiring a certified EHR would limit the number of eligible physicians without significantly adding value to CCM services. Another commenter stated that only 1,000 physicians and other eligible health

professionals have achieved Stage 2 of Meaningful Use of certified EHR technology, compared with more than 300,000 physicians and eligible professionals who have achieved Stage 1.

Response: We continue to believe that it is necessary to require the use of EHR technology that has been certified under the ONC Health IT Certification Program as requisite for receiving separate payment for CCM services, to ensure that practitioners have adequate capabilities to allow members of the interdisciplinary care team to have timely access to the most updated information informing the care plan. We agree with commenters that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple providers trying to coordinate care, and that we should ensure common functionalities as much as possible across providers. However, we also agree with commenters who expressed concern that requiring the most recent edition of EHR certification criteria could be an impediment to the broad utilization of the CCM service. In response to comments, we are modifying our proposal regarding which edition of certified EHR technology will be required, in order to allow more flexibility as practitioners transition to the use of certified EHR technology. Accordingly, we are modifying our proposal to specify that the CCM service must be furnished using, at a minimum, the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year (hereinafter "CCM certified technology") to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). Practitioners must also use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. This will ensure that requirements for CCM billing under the PFS are consistent throughout each PFS payment year and are

automatically updated annually according to the certification criteria required for the EHR Incentive Programs. For CCM payment in CY 2015, this policy will allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria to meet the final core capabilities for CCM and to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. We are finalizing the separate provision we proposed for the electronic care plan scope of service element without modification as discussed below. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters questioned the relationship between the Meaningful Use criteria and the proposed EHR scope of service element for CCM. One commenter stated that none of the requirements for EHR capability for payment of CCM services should be tied to or related to Meaningful Use, because many of the Meaningful Use requirements do not apply to CCM. Another commenter supported what they understood to be our proposal, to require billing physicians to adopt an EHR and utilize it to meet the most recent standard for Meaningful Use. However, the commenter noted (similar to the previous commenter) that the current functionalities and standards for EHR technology required for Meaningful Use are not entirely aligned with the functionalities required for CCM, for example the commenter believed that the electronic care plan need only be shared 10 percent of the time to meet Meaningful Use measures, but that CCM would require it to be available 24/7 and to all practitioners. The commenter expressed concern that practitioners might not be able to furnish CCM as envisioned by CMS due to discrepancies with the Meaningful Use criteria, and urged CMS to adopt interoperability standards for Meaningful Use that would enable successful care coordination models. Another commenter recommended that enforcement of the proposed EHR requirement

be coterminous with the enforcement of Meaningful Use Stage 2 to ensure practices have the ability to comply.

Response: Although we understand why some commenters would like for the requirements for the EHR Incentive Programs and the EHR scope of service element for CCM to be identical, we do not believe that is entirely possible because of the different nature and purpose of the respective EHR specifications. In many respects they are not comparable requirements. For example, the PFS sets payment requirements prospectively for a given calendar year, while the EHR Incentive Program may change requirements mid-year. In addition, many of the Meaningful Use measures are not relevant for the provision of CCM and we believe we should only require practitioners to adopt the certified technology that is relevant to the scope of CCM services. In their attempts to meet Meaningful Use criteria for a given year, practitioners are required to use technology certified to a specific edition(s) of certification criteria to meet the CEHRT definition, and as we discussed above we are aligning the edition required to bill CCM with the edition(s) required for Meaningful Use each year. However, it is conceivable that a practitioner could use CCM certified technology to provide and be paid for CCM in a given calendar year that will not be sufficient for achieving Meaningful Use in that same year because CCM must be furnished using at least the edition(s) of certified EHR technology required for the EHR Incentive Programs as of December 31st of the prior calendar year. Also, it is possible that a practitioner could use technology certified to an edition that qualifies for CCM payment that could also be used to achieve Meaningful Use for a given calendar year, but still not meet the objectives and associated measures of a particular stage of Meaningful Use that are required to qualify for an EHR Incentive payment or avoid a downward adjustment to payments. As the commenters noted, the Meaningful Use measures are not all

relevant to the provision of CCM services, and the practitioner may not have sufficient certified technology to support all the necessary or relevant Meaningful Use objectives and measures under the EHR Incentive Programs. Certified technology is used in different ways to meet the requirements of each program. We believe that the policy we are finalizing here aligns the CCM scope of service element to the extent appropriate with the EHR Incentive Programs to achieve maximum consistency.

Comment: Several commenters asked us to clarify the requirement for the electronic care plan in relationship to the overall requirement for a certified EHR and in relationship to the 24/7 access requirement. The commenters stated they were not sure whether these proposals were independent provisions or impacted one another. The commenters stated that if CMS intended these as independent provisions, the agency should identify objective criteria to evaluate whether a particular health IT product has adequate capabilities to meet the separate requirement for the electronic care plan. The commenters stated they were not sure whether the electronic care plan would require a certified EHR, or whether there would be an exception to use of CEHRT for the care plan. The commenters recommended flexibility in how practitioners and providers capture, develop, update and share care plan information. One commenter recommended that if practitioners must attest to use of a qualifying electronic care plan, CMS should only require a simple yes/no response to minimize billing impediments. One commenter asked us to clarify the required elements of the care plan in relation to different EHR systems.

In addition, several commenters requested that we clarify whether the care plan must be electronically accessible 24/7 to all providers treating the patient's chronic conditions, those within the billing practice, or those within the billing practice who are communicating with the patient after hours. The commenters noted that providers other than the billing practitioner may

not use the same certified EHR, so it would be unreasonable to expect the same care plan and other relevant information to be accessible to all providers at all times. Other commenters believed we proposed flexibility around the certified EHR requirement in relation to the electronic care plan, and supported this proposed flexibility.

Response: Regarding the care plan, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform (not necessarily a certified EHR) that includes an electronic care plan that is accessible at all times to the practitioners within the practice, including those who are furnishing CCM outside of normal business hours. By practitioners "within the practice," we mean any practitioners furnishing CCM services whose minutes count towards a given practice's time requirement for reporting the CCM billing code.

In addition, we proposed that the electronic care plan must be available to be shared electronically with care team members outside the practice (who are not billing for CCM). We sought to convey that practitioners could satisfy these requirements related to the care plan without using the certified EHR technology. We specified that the certified EHR technology is only required to accomplish activities described in the scope of service elements that specifically mention a medical record or EHR. We said that a full list of problems, medications and medication allergies in the certified EHR (which would follow structured recording formats) must inform the care plan, not that the care plan itself must be created or transmitted among providers using certified EHR technology. We note that this was a limited proposal compared to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the patient's full electronic medical record instead of just the care plan (78 FR 74416 through 74417).

Through separate requirements for the electronic care plan and the certified EHR, our intent was to require practitioners to use some form of electronic technology tool or service in fulfilling the care plan element (other than facsimile transmission), recognizing that certified EHR technology is limited in its ability to support electronic care planning at this time, and that practitioners must have flexibility to use a wide range of tools and services beyond certified EHR technology now available in the market to support electronic care planning. We intended that all care team members furnishing CCM services that are billed by a given practice (contributing to the minimum time required for billing) must have access to the electronic care plan at all times when furnishing CCM services. However, the electronic care plan would not have to be available at all times to other non-billing practices, recognizing that other practices may not be using compatible electronic technology or participating in a health information exchange.

We are finalizing the electronic care plan and 24/7 access elements as proposed, clarifying that to satisfy the care plan scope of service element, practitioners must electronically capture care plan information and make this information available to all care team members furnishing CCM services that are billed by a given practice (counting towards the minimum monthly service time), even when furnishing CCM outside of normal business hours. In addition, practitioners must electronically share care plan information as appropriate with other providers and practitioners who are furnishing care to the patient. We are not requiring that practitioners use a specific electronic technology to meet the requirement for 24/7 access to the care plan or its transmission, only that they use an electronic technology other than facsimile. For instance, practices may satisfy the 24/7 care plan access requirement through remote access to an EHR, web-based access to a care management application, or web-based access to a health information exchange service that captures and maintains care plan information. Likewise, we

are not requiring that practitioners use a specific electronic technology to meet the requirement to share care plan information electronically with other practitioners and providers who are not billing for CCM. For instance, practitioners may meet this sharing requirement through the use of secure messaging or participation in a health information exchange with those practitioners and providers, although they may not use facsimile transmission.

While we are not requiring that practitioners use a specific electronic technology at this time (other than not allowing facsimile), we may revisit this requirement as standards-based exchange of care plan information becomes more widely available in the future. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters asked us to clarify the relationship between the certified EHR proposal and the summary record exchange requirement. Commenters believed that CMS had cited specific regulatory provisions around exchange in the proposed rule (identified by the commenter as a Summary Record Exchange (SRE) capability tag, referring to a designation used to identify those products on the Certified Health IT Product List maintained by ONC offering technology certified to criteria around the exchange of summary care records) and should consider alternatives. The commenters were not clear as to whether they objected to what they believed to be the proposed format or the transmission method of the summary record exchange.

Response: In the CY 2014 PFS final rule with comment period, as part of the care transitions management scope of service element, we indicated that the practice must be able to facilitate the communication of relevant patient information through electronic exchange of a summary care record with other health care providers (78 FR 74418). We did not specify a standard for the "summary care record" that providers must exchange electronically, nor did we

specify a method by which providers must facilitate the communication of beneficiary information, such as use of certified EHR technology. In the CY 2015 PFS proposed rule (79 FR 40367), we proposed that the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. Under one of the specific certification criteria cited, we proposed that practitioners must use technology that meets the criterion adopted at §170.314(e)(2), which would ensure that they produce summary records formatted according to the standard adopted at §170.205(a)(3). However, we did not propose that this formatting standard must be used for the exchange of patient information, only that in furnishing CCM services, practitioners must format their summaries according to this standard. We did not propose that providers billing for CCM services must adopt any certified technology for the exchange of a summary care record, such as the transmission standard related to Direct Project Transport in § 170.314(b)(2)(ii). We recognized that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified with 2014 edition certified technology, with the exception of faxing which would not meet the proposed scope of service requirement. The 2014 edition sets specific requirements for transmission or exchange of the summary record that technology must meet for certification, and we expected that only some practitioners could adopt and use such technology in CY 2015. Therefore we did not constrain practitioners to the exchange functionality in the 2014 edition if they utilized an alternative electronic tool.

As discussed above, our final policy will allow practitioners billing the PFS for CCM services to use the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of December 31st of each calendar year preceding each PFS payment year to meet

the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). (Also practitioners must use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record). Under this final policy, practitioners must format their structured clinical summaries according to, at a minimum, the standard that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year.

We are finalizing our proposal that practitioners must communicate relevant patient information through electronic exchange of a summary care record to support transitions of care, with a clarification that practitioners do not have to use any specific content exchange standard in CY 2015. We did not propose and are not finalizing a requirement to use a specific tool or service to communicate beneficiary information, as long as providers do so electronically. We note however that faxing will not fulfill this requirement for exchange of the summary care record. We did not propose to modify our view, discussed in the CY 2014 PFS final rule with comment period, that practitioners furnishing and billing for CCM services must be able to support care transitions through the electronic exchange of beneficiary information in a summary care record (78 FR 74418). While certain 2014 edition certification criteria address a content standard and transmission method for exchange of a summary record, we continue to expect that only some practitioners could adopt and use such technology. Moreover, we recognize that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified in 2014 edition certification criteria. We continue to believe that at least for CY 2015, we should allow flexibility in the selection of the electronic tool or service that is used to transmit beneficiary information in support of care

transitions, as long as practitioners electronically share beneficiary information to support transitions of care. Finally we remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters expressed concern about requiring a certified EHR for billing CCM. The commenters were concerned that CMS would not allow the use of non-certified technologies that may be more innovative and effective than certified technologies. Commenters requested that we clarify whether only the certified EHR (and no other electronic tool) could be used to conduct CCM services, for example the use of enhanced communication methods other than telephone. One commenter stated that many times the practice will be using the certified EHR system to carry out such activities, and there are strong Meaningful Use incentives to employ the certified EHR for these activities. However, a practice may also have other capabilities and tools that would support elements of the CCM services. These commenters asked us to clarify whether the requirement to utilize certified EHR technology is a literal statement that only certified EHR technology may be used in furnishing the scope of service elements for CCM services.

Response: We continue to believe that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple practitioners trying to coordinate care. For the separately billable CCM service, we believe it is necessary to establish as part of the scope of the service a certified EHR that allows for the data capture, accessibility and sharing capabilities necessary to furnish the service. Therefore, we are finalizing our proposal to require use of CCM certified technology to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). In addition, whenever a

scope of service element references a health or medical record, CCM certified technology must be used to fulfill that scope of service element in relation to the health or medical record. We have listed above the current scope of service elements that include a reference to a health or medical record. If both CCM certified technology and other methods are available to the practitioner to fulfill the final core technology capabilities for CCM (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) or the CCM scope of service elements referencing a the health or medical record, practitioners may only use the certified capability. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: One commenter recommended that we adopt the following additional 2014 EHR certification criteria:

- Patient List Creation (45 CFR 170.314(a)(14)), which would support the required element of service for preventive services and routine appointments, and could help provide registry types of functions for the practice to use in managing patients who have agreed to participate in the chronic care management service.
- Patient-Specific Education Resources (§170.314(a)(15)), which would help assure the ability to provide the patient with relevant educational materials about their chronic disease conditions.
- Clinical Reconciliation (§170.314(b)(4)), which would serve support the medication reconciliation requirement and the requirement to review patient adherence to their medication regime.
- View/Download/Transmit to a 3rd Party (§170.314(e)(1)), which would enable

patients to access their own electronic health record and have access to information related to their care at their own convenience.

- Secure Messaging, Ambulatory Setting Only (§170.314(e)(3)).

Response: Some of these 2014 certification criteria are not relevant (have no corollary) in the 2011 certification criteria, so we would not require them because practitioners are not required to use the 2014 edition in CY 2015. In addition, we are requiring that providers use certified EHR technology to fulfill a limited number of the scope of service elements (summarized in Table 33). We are requiring the certified technology only for certain foundational elements, and believe we should avoid making the EHR requirement for CCM unnecessarily complex at this time. While we agree that the other features of certified EHR products mentioned by the commenter would certainly help many practitioners fulfill the other elements of the CCM service, practitioners may be using tools other than certified technology that are adequate for the required task(s), for example, registry tools for patient list creation, educational resources, patient portals, third party reconciliation services, and secure messaging systems.

Comment: We received many comments on the scope of service elements other than the EHR, some requesting that we implement additional standards. A few commenters said CMS should consider adding a requirement for use of community based providers through a home visit at least once every 12 months to assess the home environment and the need for community based resources, or that CMS should include home and domiciliary care, group visits and community based care. Several commenters wanted us to include “remote patient monitoring” or “patient generated health data” in the scope of services, such as daily remote monitoring of physiology and biometrics. Several commenters recommended additional tools for patient self-management

education and training, or "patient activation" tools. One commenter recommended we require a patient experience survey to assess the patient's perspective regarding the CCM services they receive. Several commenters believed we should expand the medication management and medication reconciliation element to include more comprehensive medication management and more clearly define "review of adherence" to the medication regimen.

Response: Other than the scope of service element for EHR and other electronic technology, we do not believe additional changes to the scope of service elements for CCM are warranted at this time. We are requiring certified EHR technology for certain foundational or "core" elements, including structured recording of medications and medication allergies. As finalized in the scope of service in the CY 2014 PFS final rule with comment period we are also requiring medication reconciliation with review of adherence and potential interactions, and oversight of patient self-management of medications. We believe it would be overly burdensome, especially given the broad eligible beneficiary population and final RVU inputs, to include more specific requirements related to medication management, especially when greater specificity is likely not necessary to ensure adequate care. The CCM services are by definition non-face-to-face services; therefore we are not including a requirement for home or domiciliary visits or community based care (although there is a requirement related to coordinating home and community based care). Practitioners who engage in remote monitoring of patient physiological data of eligible beneficiaries may count the time they spend reviewing the reported data towards the monthly minimum time for billing the CCM code, but cannot include the entire time the beneficiary spends under monitoring or wearing a monitoring device. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

Comment: We received many comments on the scope of service elements other than the EHR, requesting that CMS implement fewer standards. Some commenters believed that other than the "incident to" provisions, the scope of service elements are administratively burdensome and it will be difficult for physicians to adequately document that they have fulfilled the requirements. Several commenters did not believe it was necessary to require written beneficiary consent. Others asked that CMS develop model beneficiary consent forms.

Response: We understand the commenters' concerns about adequate documentation, although this issue is not unique to CCM services. We believe the additional scope of service element for the EHR and electronic sharing of the care plan and clinical summary record will create an electronic "footprint" that will facilitate documentation, including documentation of the minimum monthly amount of time spent in providing CCM services.

Regarding beneficiary consent, we believe written beneficiary consent and its documentation in the medical record is necessary because we are requiring practices to share beneficiaries' protected health information both within and outside of the billing practice in the course of furnishing CCM services and because beneficiaries will be required to pay coinsurance on non-face-to-face services. We do not believe the content or nature of the required consent is so complex that we should develop model formats. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

In summary, we are finalizing our proposal for the CCM scope of service element for EHR technology as proposed, with the following modification. We are including as an element of the separately billable CCM service the use of, at a minimum, technology certified to the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of

December 31st of the calendar year prior to the PFS payment year (CCM certified technology), to meet the final core EHR capabilities (structured recording of demographics, problems, medications, medication allergies and the creation of a structured clinical summary record) and to fulfill all activities within the final scope of service elements that reference a health or medical record. For CCM payment in CY 2015, this policy will allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria. The final scope of service elements that refer to a health or medical record, and that must be fulfilled using the CCM certified technology, are summarized in Table 33 and include the following:

- A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
- 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.
- 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.
- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

We are finalizing our proposal regarding the electronic care plan scope of service element without modification. To satisfy this element, practitioners must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within

the practice who are furnishing CCM services whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (other than by facsimile) as appropriate with other practitioners and providers who are furnishing care to the beneficiary. We are not requiring practitioners to use a specific electronic solution to furnish the care plan element of the CCM service, only that the method must be electronic and cannot include facsimile transmission.

Similarly, we are not requiring practitioners to use a specific tool or service to communicate clinical summaries in managing care transitions, as long as practitioners transmit the clinical summaries electronically, with the exception of faxing which will not fulfill the requirement for exchange of a summary care record. However practitioners must format their clinical summaries according to, at a minimum, the standard that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner. We summarize the final requirements for the CCM scope of service elements and billing requirements for CY 2015 and their relationship to the final EHR requirements in Table 33.

TABLE 33: Summary of Final CCM Scope of Service Elements and Billing Requirements for CY 2015

CCM Scope of Service Element/Billing Requirement	Certified EHR or Other Electronic Technology Requirement
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 care management services 24/7 (providing the beneficiary with a means to make timely contact with health care providers in the practice 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 practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.	None
Care management for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.	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 practice whose time counts towards the time requirement for the practice to bill the CCM code; and share care plan information electronically (other than by fax) as appropriate with other practitioners and providers.
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.

CCM Scope of Service Element/Billing Requirement	Certified EHR or Other Electronic Technology Requirement
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 practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.	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.
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

CCM Scope of Service Element/Billing Requirement	Certified EHR or Other Electronic Technology Requirement
Beneficiary consent - Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month.	None

4. Payment of CCM Services in CMS Models and Demonstrations

As discussed in section II.G., several CMS models and demonstrations address payment for care management services. The Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration and the Comprehensive Primary Care (CPC) Initiative both include payments for care management services that closely overlap with the scope of service for the new chronic care management services code. In these two initiatives, primary care practices are receiving per beneficiary per month payments for care management services furnished to Medicare fee-for-service beneficiaries attributed to their practices. We proposed that practitioners participating in one of these two models may not bill Medicare for CCM services furnished to any beneficiary attributed to the practice for purposes of participating in one of these initiatives, as we believe the payment for CCM services would be a duplicative payment for substantially the same services for which payment is made through the per beneficiary per month payment. However, we proposed that these practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice for the purpose of the practice's participation as part of one of these initiatives. As the Innovation Center implements new models or demonstrations that include payments for care management services, or as changes take place that affect existing models or demonstrations, we will address potential overlaps with the CCM service and seek to implement appropriate reimbursement policies. We solicited comments on this proposal. We also solicited comments on the extent to which these services may not actually be duplicative and, if so, how our reimbursement policy could be tailored to address those situations.

We received several comments that either supported or did not oppose our proposed policy regarding the payment of CCM services in CMS models and demonstrations that also pay for care management services.

The following is a summary of the other comments we received regarding our proposals on reimbursement policies.

Comment: Two commenters requested that we reconsider our proposed policy to exclude demonstration practitioners from billing for CCM services to ensure that these practitioners are not disadvantaged relative to those practitioners who do not participate in demonstrations or models.

Response: Our proposed policy does not exclude practitioners participating in demonstrations or models from billing for CCM services. To reiterate, practitioners participating in demonstrations or models may bill Medicare for CCM services for beneficiaries who are not attributed to the practices for purposes of participating in either the MAPCP or CPC. For beneficiaries who are not attributed to the practice, no care management payment is made under the MAPCP or CPC models. If the beneficiary otherwise meets the criteria for CCM services, the practitioner may furnish and bill Medicare for CCM. However, Medicare will not pay practitioners participating in MAPCP or CPC for CCM services furnished to beneficiaries attributed to the practice for the purpose of the practice's participation in either these models. We believe we have created a pathway to enable practitioners participating in CPC or MAPCP to bill Medicare for the CCM services, as not all beneficiaries treated in a practice will be attributed to the practice.

Comment: We received two comments expressing concern for confusion that might occur regarding the interaction of CCM services and the CPC model.

Response: We acknowledge that the Innovation Center will need to engage in extensive communications efforts with practitioners participating in either CPC or MAPCP to inform them of our policies regarding billing for CCM services.

Comment: One individual commented that payment for CCM "should not be

constrained" by the payment in a demonstration. The commenter also said, "The two payments are completely unrelated and are made for different purposes to very different physician practices. Also, we do not believe it is possible to know with certainty whether there is overlap between a fee-for-service chronic care management payment and a payment for care coordination in a demonstration."

Response: The proposed policy aims not to constrain practitioners voluntarily participating in Innovation Center models and demonstrations, specifically CPC and MAPCP, by allowing them to bill Medicare for CCM services furnished to beneficiaries for whom they are not receiving payments as part of these initiatives. We expect the practitioners participating in these initiatives will be eligible to bill the CCM service for some beneficiaries, as there is overlap between elements of the CCM service and the models. For example, the CPC model requires practitioners to use electronic health records that have been certified by the National Coordinator for Health Information Technology, provide patients with 24/7 access to the practice, ensure continuity of care with a designated practitioner or care team for each patient, provide care management that includes a systematic assessment of patient needs, use patient-centered care plans, and give enhanced opportunities for patient and caregiver communications. Similarly, the MAPCP demonstration is testing the patient-centered medical home model, which focuses on care management, continuity of care, and care coordination. All practitioners, who are voluntarily participating in these initiatives, receive quarterly reports indicating which beneficiaries have been attributed to their practices. After reviewing and comparing the features of the CPC and MAPCP models with the CCM service, we continue to be convinced that there is overlap. The CCM service provides appropriate payment for care management and care coordination furnished to beneficiaries with multiple chronic conditions within the current fee-for-service Medicare program, while Innovation Center models and demonstrations test

alternative payment methods that promote less reliance on a fee-for-service funding stream and support primary care delivery transformation at the practice level to identify potential future alternative approaches to payment.

In response to these comments, we will engage in extensive communications explaining to practices participating in CMMI models and demonstrations, specifically the CPC and MAPCP initiatives, the policies related to care management payments under these initiatives and the CCM service. We continue to believe the payment for CCM services would be a duplicative payment for substantially the same services included in the per beneficiary per month payment under the CPC and MAPCP models. Therefore, we are finalizing our proposed policy that CMS will not pay practitioners participating in one of these two initiatives for CCM services furnished to any beneficiary attributed by the initiative to the practice. These practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed by the initiative to the practice. As the Innovation Center implements new models or demonstrations that include payments for care management services, or as changes take place that affect existing models or demonstrations, we will address potential overlaps with the CCM service and seek to implement appropriate payment policies.

I. Outpatient Therapy Caps for CY 2015

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 once-exempt outpatient hospital setting (effective October 1, 2012) and critical access hospitals (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 2014 therapy cap of $1,920 by the CY 2015 MEI of 0.8 percent and rounding to the nearest $10.00 results in a CY 2015 therapy cap amount of $1,940.

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 (MIEA-TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, TPTCCA, MCTRJCA, ATRA and PAMA). The Agency's current authority to provide an exceptions process for therapy caps expires on March 31, 2015.

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.

Under section 1833(g)(5)(C) of the Act, we are 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. The statutorily required manual medical review expires March 31, 2015, consistent with the expiration of the Agency's authority to provide an exceptions process for the therapy caps. For information on the manual medical review process, go to www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html.

J. Definition of Colorectal Cancer Screening Tests

As discussed in the proposed rule (79 FR 40368), section 1861(pp) of the Act defines "colorectal cancer screening tests" and, under section 1861(pp)(1)(C), a "screening colonoscopy" is one of the recognized procedures. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to modify the tests and procedures covered under this subsection, "with such frequency and payment limits, as the Secretary determines appropriate," in consultation with appropriate organizations. The current definition of "colorectal cancer screening tests" at §410.37(a)(1) includes "screening colonoscopies." Until recently, the prevailing practice for screening colonoscopies has been moderate sedation provided intravenously by the endoscopist, without resort to separately provided anesthesia.[3] Based on this prevailing practice, payment for moderate sedation has accordingly been bundled into the payment for the colorectal cancer screening tests, (for example, G0104, G0105). For these procedures, because moderate sedation is bundled into the payment, the same physician cannot also report a sedation code. An anesthesia service can be billed by a second physician.

However, a recent study in The Journal of the American Medical Association (JAMA) cited an increase in the percentage of colonoscopies and upper endoscopy procedures furnished using an anesthesia professional, from 13.5 percent in 2003 to 30.2 percent in 2009 within the Medicare population, with a similar increase in the commercially-insured population.[4] A 2010 study projected that the percentage of this class of procedures involving an anesthesia professional would grow to 53.4 percent by 2015.[5] These studies suggest that the prevailing practice for endoscopies in general and screening colonoscopies in particular is undergoing a

[3] Faulx, A. L. et al. (2005). The changing landscape of practice patterns regarding unsedated colonoscopy and propofol use: A national web survey. *Gastrointestinal Endoscopy, 62.* 9-15.
[4] Liu H, Waxman DA, Main R, Mattke S. Utilization of Anesthesia Services during Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009. (2012). *JAMA*, 307(11):1178-1184.
[5] Inadomi, J. M. et al. (2010). Projected increased growth rate of anesthesia professional–delivered sedation for colonoscopy and EGD in the United States: 2009 to 2015. Gastrointestinal Endoscopy, 72, 580-586.

transition, and that anesthesia separately provided by an anesthesia professional is becoming the prevalent practice. In preparation for the proposed rule, we reviewed these studies and analyzed Medicare claims data. We saw the same trend in screening colonoscopies for Medicare beneficiaries with 53 percent of the screening colonoscopies for Medicare claims submitted in 2013 had a separate anesthesia claim reported.

In light of these developments, we expressed our concern in the proposed rule that the mere reference to "screening colonoscopies" in the definition of "colorectal cancer screening tests" has become inadequate. Indeed, we were convinced that the growing prevalence of separately provided anesthesia services in conjunction with screening colonoscopies reflects a change in practice patterns. Therefore, consistent with the authority delegated by section 1861(pp)(1)(D) of the Act, we proposed to revise the definition of "colorectal cancer screening tests" to adequately reflect these new patterns. Specifically, we proposed to revise the definition of "colorectal cancer screening tests" at §410.37(a)(1)(iii) to include anesthesia that is separately furnished in conjunction with screening colonoscopies (79 FR 40369).

We also stated that our proposal to revise the definition of "colorectal cancer screening tests" in this manner would further reduce our beneficiaries' cost-sharing obligations under Part B. Screening colonoscopies have been recommended with a grade of A by the United States Preventive Services Task Force (USPSTF) and §410.152(l)(5) provides that Medicare Part B pays 100 percent of the Medicare payment amount established under the PFS for colorectal cancer screening tests except for barium enemas (which do not have a grade A or B recommendation from the USPSTF). This regulation is based on section 1833(a)(1) of the Act, as amended by section 4104 of the Affordable Care Act, which requires 100 percent Medicare payment of the fee schedule amount for those "preventive services" that are appropriate for the individual and are recommended with a grade of A or B by the USPSTF. Section 4104 of the

Affordable Care Act amended section 1833(a)(1) of the Act to effectively waive any Part B coinsurance that would otherwise apply for certain recommended preventive services, including screening colonoscopies For additional discussion of the impact of section 4104 of the Affordable Care Act, and our prior rulemaking based on this provision see the CY 2011 PFS final rule with comment period (75 FR 73412 through 73431). We also noted that under §410.160(b)(7) colorectal cancer screening tests are not subject to the Part B annual deductible and do not count toward meeting that deductible.

In implementing the amendments made by section 4104 of the Affordable Care Act, we did not provide at that time for waiving the Part B deductible and coinsurance for covered anesthesia services separately furnished in conjunction with screening colonoscopies. At that time, we believed that our payment for the screening colonoscopy, which included payment for moderate sedation services, reflected the typical screening colonoscopy. Under the current regulations, Medicare beneficiaries who receive anesthesia from a different professional than the one furnishing the screening colonoscopy would be incurring costs for the coinsurance and deductible under Part B for those separate services. With the changes in the standard of care and shifting practice patterns toward increased use of anesthesia in conjunction with screening colonoscopy, beneficiaries who receive covered anesthesia services from a different professional than the one furnishing the colonoscopy would incur costs for any coinsurance and any unmet part of the deductible for this component of the service. However, our proposed revision to the definition of "colorectal cancer screening tests" would lead to Medicare paying 100 percent of the fee schedule amounts for screening colonoscopies, including any portion attributable to anesthesia services furnished by a separate practitioner in conjunction with such tests, under §410.152(l)(5). Similarly, this revision would also mean that expenses incurred for a screening colonoscopy, and the anesthesia services furnished in conjunction with such tests, will not be

subject to the Part B deductible and will not count toward meeting that deductible under §410.160(b)(7). We believe the proposal encourages more beneficiaries to obtain a screening colonoscopy, which is consistent with the intent of the statutory provision to waive Medicare cost-sharing for certain recommended preventive services, and is consistent with the authority delegated to the Secretary in section 1861(pp)(1)(D) of the Act.

In light of the changing practice patterns for screening colonoscopies, continuing to require Medicare beneficiaries to bear the deductible and coinsurance expenses for separately billed anesthesia services furnished and covered by Medicare in conjunction with screening colonoscopies could become a significant barrier to these essential preventive services. As we noted when we implemented the provisions of the Affordable Care Act waiving the Part B deductible and coinsurance for these preventive services, the goal of these provisions was to eliminate financial barriers so that beneficiaries would not be deterred from receiving them (75 FR 73412). Therefore, we proposed to exercise our authority under section 1861(pp)(1)(D) of the Act to revise the definition of colorectal cancer screening tests to encourage beneficiaries to seek these services by extending the waiver of coinsurance and deductible to anesthesia or sedation services furnished in conjunction with a screening colonoscopy.

We noted in the proposed rule (79 FR 40370) that, in implementing these proposed revisions to the regulations, it would be necessary to establish a modifier for use when billing the relevant anesthesia codes for services that are furnished in conjunction with a screening colonoscopy, and thus, qualify for the waiver of the Part B deductible and coinsurance. Therefore, we noted that we would provide appropriate and timely information on this new modifier and its proper use so that physicians will be able to bill correctly for these services when the revised regulations become effective. We also noted that the valuation of colonoscopy codes, which include moderate sedation, would be subject to the same proposed review as other

codes that include moderate sedation, as discussed in section II.B.6 of this final rule with comment period.

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

Comment: The majority of commenters strongly supported finalizing our proposal to revise the definition of "colorectal cancer screening tests" at §410.37(a)(1)(iii) to include anesthesia that is furnished in conjunction with screening colonoscopies. However, one commenter expressed concern about the timing of the proposal, and specifically that it leaves little time for implementation in CY 2015. Therefore, the commenter recommended that the proposal should be considered for implementation in CY 2016.

Response: We appreciate the support for our proposal and are finalizing it as proposed. Specifically, we are revising the definition of "colorectal cancer screening tests" at §410.37(a)(1)(iii) to include anesthesia that is furnished in conjunction with screening colonoscopies. We disagree with the recommendation to delay implementation until CY 2016. The proposed implementation on January 1st following the finalization of the policy in the final rule follows the usual PFS schedule for implementation of payment changes. We are not aware of a reason for deviating from the usual schedule for this policy. Therefore, we are implementing this final rule, effective January 1, 2015.

Comment: Many commenters urged us to extend our proposed revision, by identifying a way under our existing authority to redefine colorectal cancer screening to include screening colonoscopy with removal of polyp, abnormal growth, or tissue during the screening encounter. Commenters stated that there is already substantial confusion among beneficiaries about why colonoscopy with polyp removal requires payment of coinsurance, while colonoscopy without polyp removal does not. The commenters maintained that our proposal to include anesthesia that is separately furnished in conjunction with screening colonoscopies within the definition of

screening colonoscopy would only cause additional confusion, unless screening colonoscopies with removal of polyp, along with any anesthesia separately furnished in conjunction with such procedures, are also included within the definition. Because our proposal rule did not seek to make changes to our policies with respect to diagnostic colonoscopies, the commenters were concerned that, beneficiaries may be liable for part B coinsurance for both diagnostic colonoscopy and any anesthesia furnished in conjunction with the colonoscopy when a polyp is removed. Commenters also stated that extending our proposal in this manner would be good public policy, because it would reduce the disincentives to this essential preventive service posed by possible liability for coinsurance if a polyp is discovered and removed during a screening colonoscopy. The commenters also emphasized that further extending the definition in this way would remove an inconsistency between Medicare policy and the new requirements for private health plans that prohibit the imposition of cost sharing when a polyp is removed under the Affordable Care Act.

Response: We understand the commenters' concerns, however, we do not have the authority to adopt the recommended revisions by regulation.

Our authority is limited by the language of the Medicare Act. Specifically, section 1834(d)(3)(D) of the Act states that, "[i]f during the course of such a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal." As a result of this statutory provision, when an anticipated screening colonoscopy ends up involving a biopsy or polyp removal, Medicare cannot pay for this procedure as a screening colonoscopy. In these circumstances, Medicare pays 80 percent of the diagnostic colonoscopy procedure and the beneficiary is responsible for paying Part B coinsurance. Under the statute, when a polyp or

other growth is removed, beneficiaries are responsible for Part B coinsurance for the diagnostic colonoscopy, and similarly, any Part B coinsurance for any covered anesthesia.

Comment: Commenters stated that the proposal was not clear on how the deductible will be treated in the case of anesthesia services when a polyp or other tissue is removed during a screening colonoscopy.

Response: Section 1833(b)(1) of the Act, as amended by section 4104(c) of the Affordable Care Act, waives the Part B deductible for "colorectal screening tests regardless of the code 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 a screening test." We explained this provision in the CY 2011 PFS final rule with comment period (75 FR 73431). We apply this policy to any surgical service furnished on the same date as a planned colorectal cancer screening test. Our regulations at §410.152(l)(5) already require Medicare Part B to pay 100 percent of the Medicare payment amount for colorectal cancer screening tests (excluding barium enema). The statutory waiver of deductible will apply to the anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during a colonoscopy. As in the case of the physician furnishing the colonoscopy service, the anesthesia professional reporting the anesthesia in conjunction with the colonoscopy where a polyp is removed would also report the PT modifier.

Comment: Commenters urged CMS to provide guidance as to whether CPT code 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum) would be billed with a modifier to indicate whether the procedure was screening or not.

Response: Effective January 1, 2015, beneficiary coinsurance and deductible do not apply to the following anesthesia claim lines billed when furnished in conjunction with screening colonoscopy services and billed with the appropriate modifier (33): 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum). Anesthesia professionals who furnish a separately payable anesthesia service in conjunction with a colorectal cancer screening test should include the 33 modifier on the claim line with the anesthesia service. As noted above in situations that begin as a colorectal cancer screening test, but for which another service such as colonoscopy with polyp removal is actually furnished, the anesthesia professional should report a PT modifier on the claim line rather than the 33 modifier.

Comment: Several commenters recommended that we not only finalize the revised definition of "colorectal cancer screening tests," but also take steps to ensure that our Medicare Administrative Contractors (MACs) are not inappropriately taking actions that have the effect of nullifying some or much of the intended benefit of this policy change. Specifically, these commenters requested that we prevent the current efforts by one or more Medicare contractors to limit Medicare coverage for anesthesia services furnished during a screening colonoscopy by an anesthesia professional. Another commenter urged us to clarify that this proposed expanded definition of colorectal cancer screening to include anesthesia services should not be construed to override or preempt existing or planned coverage policies on the appropriate use of these services by MACs.

Response: This final rule with comment period establishes national policy and takes precedence over any local coverage policy that limits Medicare coverage for anesthesia services furnished during a screening colonoscopy by an anesthesia professional.

K. Payment of Secondary Interpretation of Images

In general, Medicare makes one payment for the professional component of an imaging service for each technical component (TC) service that is furnished. Under "unusual circumstances," physicians can bill for a secondary interpretation using modifier -77, for instance, when an emergency room physician conducts an x-ray, provides an interpretation, identified a questionable finding, and subsequently requests a second interpretation from a radiologist to inform treatment decisions. In all cases, a "professional component" (PC) interpretation service should only be billed for a full interpretation and report, rather than a "review," which is paid for as part of an E/M payment.

In recent years, technological advances such as the integration of picture and archiving communications systems across health systems, growth in image sharing networks and health information exchange platforms through which providers can share images, and consumer-mediated exchange of images, have greatly increased physicians' access to existing diagnostic-quality radiology images. Accessing and utilizing these images to inform the diagnosis and record an interpretation in the medical record may allow physicians to avoid ordering duplicative tests.

We solicited comments on the appropriateness of more routine billing for secondary interpretations, although we did not propose to make any changes to the treatment of these services in 2015. We wanted to determine whether there were an expanded set of circumstances under which more routine Medicare payment for a second PC for radiology services would be appropriate, and whether such a policy would be likely to reduce the incidence of duplicative advanced imaging studies.

To achieve that goal, we solicited comments on the following: the circumstances under which physicians are currently conducting secondary interpretations and whether they are

seeking payment for these interpretations; whether more routine payment for secondary interpretations should be restricted to certain high-cost advanced diagnostic imaging services; considerations for valuing secondary interpretation services; the settings in which secondary interpretations chiefly occur; and considerations for operationalizing more routine payment of secondary interpretations in a manner that would minimize burden on providers and others.

Comment: Many commenters responded to our secondary interpretation solicitation. In addition to comments on the merits of the proposals, commenters also provided helpful information about how to implement this policy. Commenters offered diverse opinions on the time period for which an existing image would be pertinent in support of a secondary interpretation. Most commenters were in agreement that cost savings would be derived from the implementation of a secondary interpretation policy but there was no consensus as to the amount of such savings. Moreover, many commenters pointed out that they were already furnishing secondary interpretations and would appreciate adoption of a policy that would allow them to receive payment for these services.

Response: We thank all the commenters for their input. Any changes to our current policy on allowing physicians to more routinely bill for secondary interpretations of images will be addressed in future rulemaking.

L. Conditions Regarding Permissible Practice Types for Therapists in Private Practice

Section 1861(p) of the Act defines outpatient therapy services to include physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services furnished by qualified occupational therapists, physical therapists, and speech-language pathologists in their offices and in the homes of beneficiaries. The regulations at §§410.59(c), 410.60(c), and 410.62(c) set forth special provisions for services furnished by therapists in private practice, including basic qualifications necessary to qualify as a supplier of OT, PT, and SLP services, respectively. As part of these basic qualifications, the current regulatory language includes descriptions of the various practice types for therapists' private practices. Based on our review of these three sections of our regulations, we became concerned that the language is not as clear as it could be – especially with regard to the relevance of whether a practice is incorporated. The regulations appear to make distinctions between unincorporated and incorporated practices, and some practice types are listed twice. Accordingly, we proposed changes to the regulatory language to remove unnecessary distinctions and redundancies within the regulations for OT, PT, and SLP. We noted that these changes are for clarification only, and do not reflect any change in our current policy.

To consistently specify the permissible practice types (a solo practice, partnership, or group practice; or as an employee of one of these) for suppliers of outpatient therapy services in private practice (specifically for occupational therapists, physical therapists and speech-language pathologists), we proposed to replace the regulatory text at §410.59(c)(1)(ii)(A) through (E), §410.60(c)(1)(ii)(A) through (E), and §410.62(c)(1)(ii)(A) through (E) and to replace it with language listing the permissible practice types without limitations for incorporated or unincorporated.

Comment: We received comments from two therapist membership associations supporting our proposed changes to the regulations. Both commenters agree that the proposed language more consistently and accurately reflects the permissible practice types for therapists in private practice.

Another commenter representing a membership association of rehabilitation physicians told us that, rather than clarifying or simplifying the existing regulations, the proposed language is more ambiguous. The commenter urged us to clarify that our proposed language would continue to allow therapists in private practice to be employed by physician groups as specified in current provisions.

Response: We appreciate the commenters' support for our proposal. With regard to the commenter that expressed concern about the clarity of the proposed regulation text as to whether therapists in private practice can be employed by a physician group, we acknowledge that the current regulation explicitly permits that practice arrangement. However, we believe that our proposed language describing the practice arrangements of private practice therapists–a solo practice, partnership, or group practice; or as an employee of one of these–clearly continues to permit therapists to practice as an employee of a physician group, whether or not incorporated. We believe the reference in the proposed regulation to "group practice" is sufficiently broad to encompass a physician group, and thus permits therapists in private practice to practice as employees of these groups, where permissible under state law.

Therefore, we are finalizing our proposed changes to the regulations for permissible practice types for therapists in private practice at §410.59(c)(1)(ii)(A) through (E), §410.60(c)(1)(ii)(A) through (E), and §410.62(c)(1)(ii)(A) through(E).

M. Payments for Practitioners Managing Patients on Home Dialysis

In the CY 2005 PFS final rule with comment period (69 FR 66357 through 66359), we established criteria for furnishing outpatient per diem ESRD-related services in partial month scenarios. We specified that use of per diem ESRD-related services is intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the monthly capitation payment (MCP), and that use of the per diem services is limited to the circumstances listed below.

- Transient patients – Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient received a kidney transplant.
- Patients who have a permanent change in their MCP physician during the month.

Additionally, we provided billing guidelines for partial month scenarios in the Medicare claims processing manual, publication 100-04, chapter 8, section 140.2.1. For center-based patients, we specified that if the MCP practitioner furnishes a complete assessment of the ESRD beneficiary, the MCP practitioner should bill for the full MCP service that reflects the number of visits furnished during the month. However, we did not extend this policy to home dialysis (less than a full month) because the home dialysis MCP service did not include a specific frequency of required patient visits. In other words, unlike the ESRD MCP service for center-based patients, a visit was not required for the home dialysis MCP service as a condition of payment.

In the CY 2011 PFS final rule with comment period (75 FR 73295 through 73296), we changed our policy for the home dialysis MCP service to require the MCP practitioner to furnish at least one face-to-face patient visit per month as a condition of payment. However, we

inadvertently did not modify our billing guidelines for home dialysis (less than a full month) to be consistent with partial month scenarios for center-based dialysis patients. As discussed in the CY 2015 proposed rule (79 FR 40371) stakeholders have recently brought this inconsistency to our attention. After reviewing this issue, we proposed to allow the MCP physician or practitioner to bill for the age appropriate home dialysis MCP service (as described by HCPCS codes 90963 through 90966) for the home dialysis (less than a full month) scenario if the MCP practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face patient visit. For example, if a home dialysis patient was hospitalized during the month and at least one face-to-face outpatient visit and complete monthly assessment was furnished, the MCP practitioner should bill for the full home dialysis MCP service. We explained that this proposed change to home dialysis (less than a full month) would provide consistency with our policy for partial month scenarios pertaining to patients dialyzing in a dialysis center. We also stated that if this proposal is adopted, we would modify the Medicare Claims Processing Manual to reflect the revised billing guidelines for home dialysis in the less than a full month scenario.

A summary of the comments on this proposal and our response is provided below.

Comment: Several stakeholders strongly supported our proposed change for practitioners managing patients on home dialysis. Specifically, the commenters stated that the proposed change in policy for the home dialysis MCP service is necessary to appropriately align practitioner payment for managing home dialysis patients with center based patients, and encouraged us to finalize the change in policy as proposed. One commenter explained that the current policy for home dialysis less than a full month requires the nephrologist to "separate out the time their home dialysis patients spend in the hospital and bill for outpatient services at a daily rate instead of the full capitated payment." The same commenter stated that "properly

aligning physician payments for managing home dialysis patients (with managing center based dialysis patients) may enable more patients to consider dialyzing at home, when appropriate."

Response: We agree with the commenters and will finalize our proposed policy change for home dialysis. We will allow the MCP practitioner to bill for the home dialysis MCP service for the home dialysis (less than a full month) scenario if the MCP practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face patient visit during the month.

N. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

(1) The estimated change in fees for physicians' services;

(2) The estimated change in the average number of Medicare fee-for-service beneficiaries;

(3) The estimated projected growth in real Gross Domestic Product per capita; and

(4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to determine the SGRs for 3 different time periods, using the best data available as of September 1 of each year. Under section 1848(f)(3) of the Act, (beginning with the FY and CY 2000 SGRs) the SGR is estimated and subsequently revised twice based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each of the 2 years following the preliminary estimate. In this final rule with comment, we are

making our preliminary estimate of the CY 2015 SGR, a revision to the CY 2014 SGR, and our final revision to the CY 2013 SGR.

a. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that "the term 'physicians' services' includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee."

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. Since that time, the statute has been amended to add new Medicare benefits. As the statute changed, we modified the definition of physicians' services for the SGR to include the additional benefits added to the statute that meet the criteria specified in section 1848(f)(4)(A).

As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of "physicians' services." Exercising this discretion, we removed physician-administered drugs from the definition of physicians' services in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary's policy decision to remove drugs from the definition of physicians' services, we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by the Medicare Administrative Contractors:

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for "drugs and biologicals which are not usually self-administered by the patient."
- Outpatient physical therapy services and outpatient occupational therapy services,
- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, nurse practitioners, and certified nurse specialists.
- Screening tests for prostate cancer, colorectal cancer, and glaucoma.
- Screening mammography, screening pap smears, and screening pelvic exams.
- Diabetes outpatient self-management training (DSMT) services.
- Medical Nutrition Therapy (MNT) services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
- X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
- Bone mass measurements.
- An initial preventive physical exam.
- Cardiovascular screening blood tests.
- Diabetes screening tests.

- Telehealth services.
- Physician work and resources to establish and document the need for a power mobility device.
- Additional preventive services.
- Pulmonary rehabilitation.
- Cardiac rehabilitation.
- Intensive cardiac rehabilitation.
- Kidney disease education (KDE) services.
- Personalized prevention plan services

b. Preliminary Estimate of the SGR for 2015

We first estimated the CY 2015 SGR in March 2014, and we made the estimate available to the MedPAC and on our website. Table 34 shows the March 2014 estimate and our current estimates of the factors included in the 2015 SGR. Our March 2014 estimate of the SGR was -3.6 percent. Our current estimate of the 2015 SGR is -13.7 percent. The majority of the difference between the March estimate and our current estimate of the CY 2015 SGR is explained by adjustments to reflect intervening legislative changes that occurred after our March estimate was prepared. Subsequent to the display of the March 2014 estimate, section 101 of the Protecting Access to Medicare Act (PAMA) of 2014 continued a 0.5 percent update to the PFS conversion factor from April 1, 2014, through December 31, 2014 (relative to the 2013 conversion factor), in place of the 24.1 percent reduction that would have occurred under the SGR system on April 1, 2014. In addition, section 101 of PAMA also provides for a 0.0 percent update for services furnished on or after January 1, 2015, through March 31, 2015. While PAMA averted the large reduction in PFS rates scheduled to occur on April 1, 2014, there will be a large reduction in PFS rates on April 1, 2015, as a result of the expiration of the temporary

0.0 percent update. . The law and regulation factor of the current estimate of the SGR is now a much larger reduction than previously estimated to account for the current law reduction in PFS rates scheduled to occur on April 1, 2015. We will provide more detail on the change in each of these factors below.

TABLE 34: CY 2015 SGR Calculations

Statutory Factors	**March Estimate**	**Current Estimate**
Fees	1.1 percent (1.011)	0.7 percent (1.007)
Enrollment	4.0 percent (1.040)	3.9 percent (1.039)
Real Per Capita GDP	0.8 percent (1.008)	0.7 percent (1.007)
Law and Regulation	-9.0 percent (0.910)	-18.1 percent (0.819)
Total	-3.6 percent (0.964)	-13.7 percent (0.863)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.007 x 1.039 x 1.007 x 0.819 = 0.863). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

c. Revised Sustainable Growth Rate for CY 2014

Our current estimate of the CY 2014 SGR is -0.8 percent. Table 35 shows our preliminary estimate of the CY 2014 SGR, which was published in the CY 2014 PFS final rule with comment period, and our current estimate. The majority of the difference between the preliminary estimate and our current estimate of the CY 2014 SGR is explained by adjustments to reflect intervening legislative changes that have occurred since publication of the CY 2014 PFS final rule with comment period. The PFS update reduction that would have occurred on April 1, 2014 was averted by PAMA, which has resulted in a much higher legislative factor than our estimate of the 2014 SGR in CY 2014 PFS final rule with comment period. We will provide more detail on the change in each of these factors below.

TABLE 35: CY 2014 SGR Calculation

Statutory Factors	Estimate from CY 2014 Final Rule	Current Estimate
Fees	0.6 percent (1.006)	0.7 Percent (1.007)
Enrollment	2.2 percent (1.022)	0.2 Percent (1.002)
Real Per Capita GDP	0.8 percent (1.008)	0.7 Percent (1.007)
Law and Regulation	-19.6 percent (0.804)	-2.4 Percent (0.976)
Total	-16.7 percent (0.833)	-0.8 Percent (0.992)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.007 x 1.002 x 1.007 x 0.976 = 0.992). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

d. Final Sustainable Growth Rate for CY 2013

The SGR for CY 2013 is 1.3 percent. Table 36 shows our preliminary estimate of the CY 2013 SGR from the CY 2013 PFS final rule with comment period, our revised estimate from the CY 2014 PFS final rule with comment period, and the final figures determined using the best available data as of September 1, 2014. We will provide more detail on the change in each of these factors below.

TABLE 36: CY 2013 SGR Calculation

Statutory Factors	Estimate from CY 2013 Final Rule	Estimate from CY 2014 Final Rule	Final
Fees	0.3 percent (1.003)	0.4 percent (1.004)	0.4 Percent (1.004)
Enrollment	3.6 percent (1.036)	1.0 percent (1.010)	0.5 Percent (1.005)
Real Per Capita GDP	0.7 percent (1.007)	0.9 percent (1.009)	0.9 Percent (1.009)
Law and Regulation	-23.3 percent (0.767)	-.05 percent (.995)	-0.5 Percent (0.995)
Total	-19.7 percent (0.803	1.8 percent (1.018)	1.3 Percent (1.013)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, 1.004 x 1.005 x 1.009 x 0.995 = 1.013). A more detailed explanation of each figure is provided in section II.N.1.e. of this final rule with comment period.

e. Calculation of CYs 2015, 2014, and 2013 SGRs

(1) Detail on the CY 2015 SGR

All of the figures used to determine the CY 2015 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement

of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(a) Factor 1– Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2015

This factor is calculated as a weighted average of the CY 2015 changes in fees for the different types of services included in the definition of physicians' services for the SGR. Medical and other health services paid using the PFS are estimated to account for approximately 89.6 percent of total allowed charges included in the SGR in CY 2015 and are updated using the percent change in the MEI. As discussed in section A of this final rule with comment period, the percent change in the MEI for CY 2015 is 0.8 percent. Diagnostic laboratory tests are estimated to represent approximately 10.4 percent of Medicare allowed charges included in the SGR for CY 2015. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI-U), which is 2.1 percent for CY 2015. Section 1833(h)(2)(A)(iv) of the Act requires that the CPI-U update applied to clinical laboratory tests be reduced by a multi-factor productivity adjustment (MFP adjustment) and, for each of years 2011 through 2015, by 1.75 percentage points (percentage adjustment). The MFP adjustment will not apply in a year where the CPI-U is zero or a percentage decrease. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule of less than zero for a year. However, the application of the percentage adjustment may result in an adjustment to the fee schedule being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. The applicable productivity adjustment for CY 2015 is -0.6 percent. Adjusting the CPI-U update by the productivity adjustment results in a 1.5 percent (2.1 percent (CPI-U) minus 0.6 percent (MFP adjustment)) update for CY 2015. Additionally, the percentage reduction of 1.75 percent is applied for CYs 2011 through 2015, as discussed previously.

Therefore, for CY 2015, diagnostic laboratory tests will receive an update of -0.3 percent. Table 37 shows the weighted average of the MEI and laboratory price changes for CY 2015.

TABLE 37: Weighted-Average of the MEI and Laboratory Price Changes for CY 2015

	Weight	Update
Physician	0.896	0.8%
Laboratory	0.104	-0.3%
Weighted-average	1.000	0.7%

We estimate that the weighted average increase in fees for physicians' services in CY 2015 under the SGR (before applying any legislative adjustments) will be 0.7 percent.

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2014 to CY 2015

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2014 to CY 2015. Services provided to Medicare Advantage (MA) plan enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average number of Medicare Part B fee-for-service enrollees will increase by 3.9 percent from CY 2014 to CY 2015. Table 38 illustrates how this figure was determined.

TABLE 38: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2014 to CY 2015 (Excluding Beneficiaries Enrolled in MA Plans)

	CY 2014	CY 2015
Overall	49.350 million	50.794 million
Medicare Advantage (MA)	16.237 million	16.389 million
Net	33.113 million	34.405 million
Percent Increase	0.2 percent	3.9 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2015 becomes known.

(c) Factor 3– Estimated Real Gross Domestic Product Per Capita Growth in CY 2015

We estimate that the growth in real GDP per capita from CY 2014 to CY 2015 will be 0.7 percent (based on the annual growth in the 10-year moving average of real GDP per capita 2006 through 2015). Our past experience indicates that there have also been changes in estimates of real GDP per capita growth made before the year begins and the actual change in real GDP per capita growth computed after the year is complete. Thus, it is possible that this figure will change as actual information on economic performance becomes available to us in CY 2015.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2015 Compared With CY 2014

The statutory and regulatory provisions that will affect expenditures for CY 2015 relative to CY 2014 are estimated to have an impact on expenditures of -18.1 percent. This is primarily due to payment reductions for eligible professionals that are not meaningful users of health information technology, the estimated reduction in PFS rates that will occur on April 1, 2015 absent a change in law, and expiration of the work GPCI floor.

(2) Detail on the CY 2014 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2014 SGR follows.

(a) Factor 1 – Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2014

This factor was calculated as a weighted-average of the CY 2014 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2014.

We estimate that services paid using the PFS account for approximately 91.1 percent of total allowed charges included in the SGR in CY 2014. These services were updated using the

CY 2014 percent change in the MEI of 0.8 percent. We estimate that diagnostic laboratory tests represent approximately 8.9 percent of total allowed charges included in the SGR in CY 2014. For CY 2014, diagnostic laboratory tests received an update of -0.8 percent.

Table 39 shows the weighted-average of the MEI and laboratory price changes for CY 2014.

TABLE 39: Weighted-Average of the MEI, and Laboratory Price Changes for CY 2014

	Weight	Update
Physician	0.911	0.8
Laboratory	0.089	-0.8
Weighted-average	1.000	0.7

After considering the elements described in Table 39, we estimate that the weighted-average increase in fees for physicians' services in CY 2014 under the SGR was 0.7 percent. Our estimate of this factor in the CY 2014 PFS final rule with comment period was 0.6 percent (78 FR 74393).

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2013 to CY 2014

We estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 0.2 percent in CY 2014. Table 40 illustrates how we determined this figure.

TABLE 40: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2013 to CY 2014 (Excluding Beneficiaries Enrolled in MA Plans)

	CY 2013	CY 2014
Overall	47.878 million	49.350 million
Medicare Advantage (MA)	14.842 million	16.237 million
Net	33.036 million	33.113 million
Percent Increase	0.5 percent	0.2 percent

Our estimate of the 0.2 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2014 compared to CY 2013, is different than our estimate of an increase of 2.2 percent in the CY 2014 PFS final rule with comment period (78 FR 74393). While our current projection based on data from 8 months of CY 2014 differs from our estimate of 2.2 percent when we had no actual data, it is still possible that our final estimate of this figure will be different once we have complete information on CY 2014 fee-for-service enrollment.

(c) Factor 3 –Estimated Real GDP Per Capita Growth in CY 2014

We estimate that the growth in real GDP per capita will be 0.7 percent for CY 2014 (based on the annual growth in the 10-year moving average of real GDP per capita (2005 through 2014)). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2014 economic performance becomes available to us in CY 2015.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2014 Compared With CY 2013

The statutory and regulatory provisions that affected expenditures in CY 2014 relative to CY 2013 are estimated to have an impact on expenditures of -2.4 percent. This impact is due to many different legislative or regulatory provisions affecting spending in 2014 relative to 2013 including a 0.5 percent update for PFS services in 2014.

(3) Detail on the CY 2013 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2013 SGR follows.

(a) Factor 1 – Changes in Fees for Physicians' Services for CY 2013

This factor was calculated as a weighted average of the CY 2013 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2013.

We estimate that services paid under the PFS account for approximately 90.1 percent of total allowed charges included in the SGR in CY 2013. These services were updated using the CY 2013 percent change in the MEI of 0.8 percent. We estimate that diagnostic laboratory tests represent approximately 9.9 percent of total allowed charges included in the SGR in CY 2013. For CY 2013, diagnostic laboratory tests received an update of -3.0 percent.

Table 41 shows the weighted-average of the MEI and laboratory price changes for CY 2013.

TABLE 41: Weighted-Average of the MEI, Laboratory, and Drug Price Changes for 2013

	Weight	Update
Physician	0.901	0.8
Laboratory	0.099	-3.0
Weighted-average	1.00	0.4

After considering the elements described in Table 41, we estimate that the weighted-average increase in fees for physicians' services in CY 2013 under the SGR (before applying any legislative adjustments) was 0.4 percent. This figure is a final one based on complete data for CY 2013.

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2012 to CY 2013

We estimate the change in the number of fee-for-service enrollees (excluding beneficiaries enrolled in MA plans) from CY 2012 to CY 2013 was 0.5 percent. Our calculation of this factor is based on complete data from CY 2013. Table 42 illustrates the calculation of this factor.

TABLE 42: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2012 to CY 2013 (Excluding Beneficiaries Enrolled in MA Plans)

	CY 2012	CY 2013
Overall	46.468 million	47.878 million
Medicare Advantage (MA)	13.587 million	14.842 million
Net	32.881 million	33.036 million
Percent Change	……	0.5 percent

(c) Factor 3 – Estimated Real GDP Per Capita Growth in CY 2013

We estimate that the growth in real per capita GDP was 0.9 percent in CY 2013 (based on the annual growth in the 10-year moving average of real GDP per capita (2004 through 2013)). This figure is a final one based on complete data for CY 2013.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2013 Compared With CY 2012.

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2013 relative to CY 2012 is -0.5 percent. This impact is due to many different legislative or regulatory provisions affecting spending in 2013 relative to 2012, including provisions of the American Taxpayer Relief Act in 2013.

2. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the MEI and the UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as "allowed expenditures") equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act. We note that the conversion factor for the time period from January 1, 2015 through March 31, 2015 will reflect a 0.0 percent update based on section 101 of PAMA.

Beginning on April 1, 2015 through December 31, 2015, the standard calculation of the PFS CF under the SGR formula would apply

The calculation of the UAF is not affected by sequestration. Pursuant to 2 U.S.C. 906(d)(6), "The Secretary of Health and Human Services shall not take into account any reductions in payment amounts which have been or may be effected under [sequestration], for purposes of computing any adjustments to payment rates under such title XVIII." Therefore, allowed charges, which are unaffected by sequestration, were used to calculate physician expenditures in lieu of Medicare payments plus beneficiary cost-sharing. As a result, neither actual expenditures nor allowed expenditures were adjusted to reflect the impact of sequestration.

a. Calculation under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following--

● Prior Year Adjustment Component. An amount determined by—

++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;

++ Dividing that difference by the amount of the actual expenditures for those services for that year; and

++ Multiplying that quotient by 0.75.

● Cumulative Adjustment Component. An amount determined by—

++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

++ Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and

++ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2015 in this case), the current CY (that is, CY 2014) and the preceding CY (that is, CY 2013) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2013 allowed expenditures in this final rule with comment).

Table 43 shows the historical SGRs corresponding to each period through CY 2015.

TABLE 43: Annual and Cumulative Allowed and Actual Expenditures for Physicians' Services from April 1, 1996 through the End of the Upcoming Calendar Year

Period	Annual Allowed Expenditures ($ in billions)	Annual Actual Expenditures ($ in billions)	Cumulative Allowed Expenditures ($ in billions)	Cumulative Actual Expenditures ($ in billions)	FY/CY SGR
4/1/96-3/31/97	47.0	47.0	47.0	47.0	.....
4/1/97-3/31/98	48.5	47.2	95.6	94.3	3.2
4/1/98-3/31/99	50.6	48.1	146.2	142.4	4.2
1/1/99-3/31/99	12.7	12.5	146.2	142.4	.....
4/1/99-12/31/99	40.5	37.2	186.7	179.6	6.9
1/1/99-12/31/99	53.2	49.7	186.7	179.6	.....
1/1/00-12/31/00	57.1	54.4	243.7	234.0	7.3
1/1/01-12/31/01	59.7	61.5	303.4	295.5	4.5
1/1/02-12/31/02	64.6	64.8	368.0	360.3	8.3
1/1/03-12/31/03	69.3	70.4	437.3	430.7	7.3
1/1/04-12/31/04	73.9	78.5	511.2	509.1	6.6
1/1/05-12/31/05	77.0	83.8	588.2	593.0	4.2
1/1/06-12/31/06	78.2	85.1	666.4	678.1	1.5
1/1/07-12/31/07	80.9	85.1	747.2	763.1	3.5
1/1/08-12/31/08	84.5	87.3	831.8	850.4	4.5
1/1/09-12/31/09	89.9	91.1	921.7	941.5	6.4
1/1/10-12/31/10	97.9	96	1,019.6	1,037.4	8.9
1/1/11-12/31/11	102.5	99.5	1,122.2	1,136.9	4.7
1/1/12-12/31/12	107.8	101.1	1,230.0	1,238.0	5.1
1/1/13-12/31/13	109.2	102.5	1,339.1	1,340.5	1.3
1/1/14-12/31/14	108.3	103.3	1,447.4	1,443.8	-0.8
1/1/15-12/31/15	93.5	N/A	1,540.9	N/A	-13.7

Notes: (1) Allowed expenditures in the first year (April 1, 1996-March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website at the following address: http://www.cms.hhs.gov/SustainableGRatesConFact/. We expect to update the website with the most current information later this month.
(2) Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.
(3) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Consistent with section 1848(d)(4)(E) of the Act, Table 43 includes our second revision of allowed expenditures for CY 2013, a recalculation of allowed expenditures for CY 2014, and our initial estimate of allowed expenditures for CY 2015. To determine the UAF for CY 2015, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2014 and the CY 2015 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making revisions to the CY 2014 and CY 2015 SGRs and CY 2014 and CY 2015 allowed

expenditures. Because we have incomplete actual expenditure data for CY 2014, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from EE10 in the following statutory formula:

$$UAF_{15} = \frac{Target_{14} - Actual_{14}}{Actual_{14}} \times 0.75 + \frac{Target_{4/96-12/14} - Actual_{4/96-12/14}}{Actual_{14} \times SGR_{15}} \times 0.33$$

UAF_{15} = Update Adjustment Factor for CY 2015= 3.0 percent

$Target_{14}$ = Allowed Expenditures for CY 2014= $108.3 billion

$Actual_{14}$ = Estimated Actual Expenditures for CY 2014 = $103.3 billion

$Target_{4/96-12/14}$ = Allowed Expenditures from 4/1/1996 - 12/31/2014 = $1,447.40 billion

$Actual_{4/96-12/14}$ = Estimated Actual Expenditures from 4/1/1996 - 12/31/2014 = $1,443.80 billion

SGR_{15}= -13.7 percent (0.863)

$$\frac{\$108.3 - \$103.3}{\$103.3} \times 0.75 + \frac{\$1{,}447.4 - \$1443.80}{\$103.3 \times .863} \times 0.33 = 4.9\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than -0.07 or greater than 0.03. Since 0.049 (4.9 percent) is greater than 0.03, the UAF for CY 2015 will be 3 percent.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1.0 to 0.03 makes the UAF equal to 1.03.

3. Percentage Change in the MEI for CY 2015

The MEI is required by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to

the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The current form of the MEI was detailed in the CY 2014 PFS final rule (78 FR 74264), which revised and reclassified certain cost categories, price proxies, and expense categories.

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2006 base year weights, is comprised of two broad categories: (1) physician's own time; and (2) physician's practice expense (PE).

The physician’s compensation (own time) component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: (1) wages and salaries; and (2) fringe benefits.

The physician’s practice expense (PE) category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff (who cannot bill independently) and other nonlabor inputs. The physician's PE component also includes the following categories of nonlabor inputs: office expenses; medical materials and supplies; professional liability insurance; medical equipment; medical materials and supplies; and other professional expenses.

Table 44 lists the MEI cost categories with associated weights and percent changes for price proxies for the CY 2015 update. The CY 2015 non-productivity adjusted MEI update is 1.7 percent and reflects a 1.9 percent increase in physician’s own time and a 1.5 percent increase in physician’s PE. Within the physician’s PE, the largest increase occurred in postage, which increased 5.4 percent.

For CY 2015, the increase in the MEI is 0.8 percent, which reflects an increase in the non-productivity adjusted MEI of 1.7 percent and a productivity adjustment of 0.9 percent (which is based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity). The BLS is the agency that publishes the official measure of private non-farm business MFP. Please see http://www.bls.gov/mfp, which is the link to the BLS historical published data on the measure of MFP.

TABLE 44: Increase in the Medicare Economic Index Update for CY 2015[1]

Revised Cost Category	2006 Revised Cost Weight (percent)[2]	CY15 Update (percent)
MEI Total, productivity adjusted	100.000	0.8
Productivity: 10-year moving average of MFP[1]	N/A[5]	0.9
MEI Total, without productivity adjustment	100.000	1.7
Physician Compensation[3]	50.866	1.9
Wages and Salaries	43.641	1.9
Benefits	7.225	2.0
Practice Expense	49.134	1.5
Non-physician compensation	16.553	1.8
Non-physician wages	11.885	1.8
Non-health, non-physician wages	7.249	2.0
Professional & Related	0.800	1.9
Management	1.529	2.2
Clerical	4.720	1.9
Services	0.200	1.2
Health related, non-physician wages	4.636	1.5
Non-physician benefits	4.668	1.9
Other Practice Expense	32.581	1.4
Utilities	1.266	4.0
Miscellaneous Office Expenses	2.478	1.0
Chemicals	0.723	-1.1
Paper	0.656	3.3
Rubber & Plastics	0.598	1.0
All other products	0.500	1.7
Telephone	1.501	0.0
Postage	0.898	5.4
All Other Professional Services	8.095	1.7
Professional, Scientific, and Tech. Services	2.592	1.8
Administrative and support & waste	3.052	1.9
All Other Services	2.451	1.2
Capital	10.310	1.8
Fixed	8.957	1.9
Moveable	1.353	0.8
Professional Liability Insurance[4]	4.295	-0.1
Medical Equipment	1.978	-0.3
Medical supplies	1.760	-0.2

[1] The forecasts are based upon the latest available Bureau of Labor Statistics data on the 10-year average of BLS private nonfarm business multifactor productivity published on July 9, 2014. (http://www.bls.gov/news.release/prod3.nr0.htm)

[2] The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To

determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) over all cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

[3] The measures of Productivity, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics Web site at http://stats.bls.gov.

[4] Derived from a CMS survey of several major commercial insurers.

[5] Productivity is factored into the MEI categories as an adjustment; therefore, no explicit weight exists for productivity in the MEI.

4. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2015

The CY 2015 PFS CF for January 1, 2015 through March 31, 2015 is $35.8013. The CY 2015 PFS CF for April 1, 2015 through December 31, 2015 is $28.2239. The CY 2015 national average anesthesia CF for January 1, 2015 through March 31, 2015 is $22.5550 The CY 2015 national average anesthesia CF for April 1, 2015 through December 31, 2015 is $17.7913.

a. PFS Update and Conversion Factors

(1) CY 2014 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by multiplying the CF for the previous year by the percentage increase in the MEI less productivity times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

(2) CY 2015 PFS Conversion Factors

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) provided a 1-year increase in the CY 2007 CF and specified that the CF for CY 2008 must be computed as if the 1-year increase had never applied.

Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) provided a 6-month increase in the CY 2008 CF, from January 1, 2008, through June 30, 2008,

and specified that the CF for the remaining portion of CY 2008 and the CFs for CY 2009 and subsequent years must be computed as if the 6-month increase had never applied.

Section 131 of the MIPPA extended the increase in the CY 2008 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2009 CF, and specified that the CFs for CY 2010 and subsequent years must be computed as if the increases for CYs 2007, 2008, and 2009 had never applied.

Section 1011(a) of the DODAA and section 5 of the TEA specified a zero percent update for CY 2010, effective January 1, 2010 through March 31, 2010.

Section 4 of the Continuing Extension Act of 2010 (CEA) extended the zero percent update for CY 2010 through May 31, 2010.

Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010.

Section 2 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. No. 111-286) extended the 2.2 percent update through the end of CY 2010.

Section 101 of the MMEA provided a zero percent update for CY 2011, effective January 1, 2011 through December 31, 2011, and specified that the CFs for CY 2012 and subsequent years must be computed as if the increases in previous years had never applied.

Section 301 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) provided a zero percent update effective January 1, 2012 through February 29, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 3003 of the Middle Class Tax Relief and Job Creation Act of 2012 (Job Creation Act) provided a zero percent update effective March 1, 2012 through December 31, 2012, and

specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 601 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112-240) provided a zero percent update for CY 2013, effective January 1, 2013 through December 31, 2013, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Section 1101 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) provided a 0.5 percent update to the PFS CF, effective January 1, 2014 through March 31, 2014 and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Section 101 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93) (PAMA) extended this 0.5 percent update through December 31, 2014. Section 101 of the PAMA also provides a 0.0 percent update for services furnished on or after January 1, 2015, through March 31, 2015, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Therefore, under current law, the CF that would be in effect in CY 2014 had the prior increases specified above not applied is $27.2006.

In addition, when calculating the PFS CF for a year, 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 more than $20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2015 RVU changes would result in an increase in Medicare physician expenditures of more than $20 million. Accordingly, we are decreasing the CF by 0.06 percent

to offset this estimated increase in Medicare physician expenditures due to the CY 2015 RVU changes.

For January 1, 2015 through March 31, 2015, the PFS update will be 0.0 percent consistent with section 101 of PAMA. After applying the budget neutrality adjustment described above, the conversion factor for January 1, 2015 through March 31, 2015 will be $35.8013.

After March 31, 2015 the standard calculation of the PFS CF under the SGR formula would apply. Therefore, from April 1, 2015 through December 31, 2015 the conversion factor would be $28.2239. This final rule with comment period announces a reduction to payment rates for physicians' services of 21.2 percent during this time period in CY 2015 under the SGR formula.

By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We will continue to work with Congress to fix this untenable situation so doctors and beneficiaries no longer have to worry about the stability and adequacy of payments from Medicare under the PFS.

We illustrate the calculation of the CY 2015 PFS CF in Table 45.

TABLE 45: Calculation of the CY 2015 PFS CF

January 1, 2015 through March 31, 2015		
Conversion Factor in effect in CY 2014		$35.8228
Update	0.0 percent (1.00)	
CY 2015 RVU Budget Neutrality Adjustment	-0.06 percent (0.9994)	
CY 2015 Conversion Factor (1/1/2015 through 3/31/2015)		**$35.8013**
April 1, 2015 through December 31, 2015		
Conversion Factor in effect in CY 2014		$35.8228
CY 2014 Conversion Factor had statutory increases not applied		$27.2006
CY 2015 Medicare Economic Index	0.8 percent (1.008)	
CY 2015 Update Adjustment Factor	-3.0 percent (1.03)	
CY 2015 RVU Budget Neutrality Adjustment	-0.06 percent (0.9994)	
CY 2015 Conversion Factor (4/1/2015 through 12/31/2015)		**$28.2239**
Percent Change in Conversion Factor on 4/1/2015 (relative to the CY 2014 CF)		**-21.2%**
Percent Change in Update (without budget neutrality adjustment) on 4/1/2015 (relative to the CY 2014 CF)		**-20.9%**

We note payment for services under the PFS will be calculated as follows:

Payment = [(Work RVU x Work GPCI) + (PE RVU x PE GPCI) + (Malpractice RVU x Malpractice GPCI)] x CF.

b. Anesthesia Conversion Factors

We calculate the anesthesia CFs as indicated in Table 46. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments through an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Information regarding the anesthesia work, PE, and malpractice shares can be found at the following: https://www.cms.gov/center/anesth.asp.

The anesthesia CF in effect in CY 2014 is $22.6765. Section 101 of PAMA provides for a 0.0 percent update from January 1, 2015 through March 31, 2015. After applying the 0.9994 budget neutrality factor described above, the anesthesia CF in effect from January 1, 2015 through March 31, 2015 will be $22.5550.

The table below includes adjustments to the anesthesia CF that are analogous to the physician fee schedule CF with other adjustments that are specific to anesthesia. In order to calculate the CY 2015 anesthesia CF for April 1, 2015 through December 31, 2015, the statute requires us to calculate the CFs for all previous years as if the various legislative changes to the CFs for those years had not occurred. The resulting CF is then adjusted for the update (the MEI, less multi-factor productivity and increased by the UAF). The national average CF is then adjusted for anesthesia specific work, practice expense and malpractice factors that must be applied to the anesthesia CF as the anesthesia fee schedule does not have RVUs. Accordingly, under current law, the anesthesia CF in effect in CY 2015 for the time period from April 1, 2015 through December 31, 2015 is $17.7913. We illustrate the calculation of the CY 2015 anesthesia CFs in Table 45.

TABLE 46: Calculation of the CY 2015 Anesthesia CF

January 1, 2015 through March 31, 2015		
CY 2014 National Average Anesthesia CF		$22.6765
Update	0.0 percent (1.00)	
CY 2015 RVU Budget Neutrality Adjustment	0.0006 percent (0.9994)	
CY 2015 Anesthesia Fee Schedule Practice Expense Adjustment	0.005 percent (.99524)	
CY 2015 National Average Anesthesia CF (1/1/2015 through 3/31/2015)		**$22.5550**
April 1, 2015 through December 31, 2015		
2014 National Average Anesthesia Conversion Factor in effect in CY 2015		$22.6765
2014 National Anesthesia Conversion Factor had Statutory Increases Not Applied		$17.2283
CY 2015 Medicare Economic Index	0.8 percent (1.008)	
CY 2015 Update Adjustment Factor	3.0 percent (0.9994)	
CY 2015 Budget Neutrality Work and Malpractice Adjustment	-0.06 percent (0.9994)	
CY 2015 Anesthesia Fee Schedule Practice Expense Adjustment	0.005 percent (.99524)	
CY 2015 Anesthesia Conversion Factor **(4/1/2015 through 12/31/2015)**		$17.7913
Percent Change from 2014 to 2015 **(4/1/2015 through 12/31/2015)**		**-21.5%**

III. Other Provisions of the Final Rule with Comment Period Regulation

A. Ambulance Extender Provisions

1. 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. Recently, section 1104(a) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions) of Pub L. 113-67, amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through March 31, 2014. Subsequently, section 104(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93, enacted on April 1, 2014) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons again through March 31, 2015. Thus, these payment add-ons also apply to covered ground ambulance transports furnished before April 1, 2015. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule (78 FR 74438 through 74439)).

These statutory requirements are 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. In the CY 2015 PFS proposed rule (79 FR 40372), we proposed to revise §414.610(c)(1)(ii) to conform the regulations to these statutory requirements. We received one comment regarding this proposal. A summary of the comment we received and our response are set forth below.

Comment: One commenter supported the implementation of the ambulance payment add-ons. The commenter also agreed that these provisions are self-implementing.

Response: We thank the commenter for their support of these provisions.

After consideration of the public comment received, we are finalizing our proposal to revise §414.610(c)(1)(ii) to conform the regulations to these statutory requirements.

2. 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 on the CMS-supplied ZIP code File.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Recently, section 1104(b) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions) of Pub. L. 113-67, amended section 1834(l)(12)(A) of the Act to extend this rural bonus through March 31, 2014. Subsequently, section 104(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93, enacted on April 1, 2014) amended section 1834(l)(12)(A) of the Act to extend this rural bonus again through March 31, 2015. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years) to ground ambulance services with dates of service before April 1, 2015 where transportation originates in a qualified rural area. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule (78 FR 74439 through 74440)).

These statutory provisions are self-implementing. Together, these statutory provisions require a 15-month extension of this rural bonus (which was previously established by the Secretary) through March 31, 2015, and do not require any substantive exercise of discretion on the part of the Secretary. In the CY 2015 PFS proposed rule (79 FR 40372), we proposed to revise §414.610(c)(5)(ii) to conform the regulations to these statutory requirements. We received one comment regarding this proposal. A summary of the comment we received and our response are set forth below.

Comment: One commenter supported the implementation of the percent increase in the

base rate of the fee schedule for transports in areas defined as super rural. The commenter also agreed with CMS that these provisions are self-implementing.

Response: We thank the commenter for their support of these provisions.

After consideration of the public comment received, we are finalizing our proposal to revise §414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

B. Changes in Geographic Area Delineations for Ambulance Payment

1. Background

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)

a. 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.

b. 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. Provisions of the Final Rule

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 urban and rural differences. This

promotes consistency across the Medicare program, and it provides for use of consistent geographic standards for Medicare payment purposes.

The current geographic areas used under the ambulance fee schedule are 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 (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, "[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 - 37252) and Census Bureau data." OMB defines an MSA as a CBSA associated with at least one urbanized area that has a population of at least 50,000, and a Micropolitan Statistical Area (referred to in this discussion as a Micropolitan Area) as a CBSA associated with at least one urban cluster that has a population of at least 10,000 but less than 50,000 (75 FR 37252). Counties that do not qualify for inclusion in a CBSA are deemed "Outside CBSAs." We note that, when referencing the new OMB geographic boundaries of statistical areas, we are using the term "delineations" consistent with OMB's use of the term (75 FR 37249).

Although the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin does contain a number of significant changes. For example, we stated in the CY 2015 PFS proposed rule (79 FR 40373) that if we adopt the revised OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. We have reviewed our findings and impacts relating to the new OMB delineations, and find no compelling reason to further delay implementation. We stated in the proposed rule that we believe 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 proposed rule (79 FR 28055), we also proposed to adopt OMB's revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. This proposal was finalized in the FY 2015 IPPS final rule (79 FR 49952). For the reasons discussed above, we believe it would be appropriate to adopt the same geographic area delineations for use under the ambulance fee schedule as are used under the IPPS and other Medicare payment systems. Thus, we proposed to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01 beginning in CY 2015 to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We 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), 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), would be recognized as rural areas.

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 are considered rural areas under the ambulance fee schedule (see §414.605). For certain rural add-ons, 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 (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as Rural-Urban Commuting Area (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 (71 FR 69714 through 69716). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13-01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service 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 2006-10 American Community Survey. We proposed to adopt the most recent modifications of the RUCA codes beginning in CY 2015, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. In the CY 2015 PFS proposed rule (79 FR 40373), we stated that if we adopt the most recent RUCA codes, many

counties that are designated as urban at the county level based on population would 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 proposed rule (79 FR 40373 through 40374), 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 (71 FR 69715), 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 (71 FR 69715), 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: ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf for additional information. Consistent with the HRSA guidelines discussed above, we proposed, beginning in CY 2015, to designate as rural areas (1) those census tracts that fall at or above RUCA level 4.0, and (2) those census tracts that fall within 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 2015 PFS proposed rule (79 FR 40374) that we continue to believe that HRSA's guidelines accurately identify rural census tracts throughout the country, and thus would be appropriate to apply for ambulance payment purposes. We invited comments on this proposal.

We stated in the CY 2015 PFS proposed rule (79 FR 40374) that 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, and 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.

Currently, section 1834(l)(12) of the Act (as amended by section 104(b) of the PAMA) specifies that, for services furnished during the period July 1, 2004 through March 31, 2015, 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). We stated in the CY 2015 PFS proposed rule (79 FR 40374) that 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.

As we stated in the CY 2015 PFS proposed rule (79 FR 40374), the adoption of the new OMB delineations and the updated RUCA codes would affect whether or not transports would be eligible for other 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)). Furthermore, under section 1834(l)(13) of the Act (as amended by section 104(a) of the PAMA), for ground ambulance transports furnished through March 31, 2015, 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)).

We stated in the CY 2015 PFS proposed rule (79 FR 40374) that if we adopt OMB's revised delineations and the updated RUCA codes, 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 are currently within urban areas) may experience increases in payment for such transports because they may be eligible for the rural adjustment factors discussed above,

while 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 are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed above.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. In the CY 2015 PFS proposed rule (79 FR 40374), we stated that, based on the latest United States Postal Service (USPS) ZIP code file, there are a total of 42,914 ZIP codes in the U.S. We stated in the proposed rule that the geographic designations for approximately 99.48 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes, and that a similar number of ZIP codes would change from rural to urban (122, or 0.28 percent) as would change from urban to rural (100, or 0.23 percent). We stated in the proposed rule that, in general, it was expected that ambulance providers and suppliers in 100 ZIP codes within 11 states may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. We stated that the state of Ohio would have the most ZIP codes changing from urban to rural with a total of 40, or 2.69 percent. We also stated in the CY 2015 PFS proposed rule that ambulance providers and suppliers in 122 ZIP codes within 22 states may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. We stated that the state of West Virginia would have the most ZIP codes changing from rural to urban (17, or 1.82 percent), while Connecticut would have the greatest percentage of ZIP codes changing from rural to urban (15 ZIP codes, or 3.37 percent). Our findings were illustrated in Table 17 of the

CY 2015 PFS proposed rule (79 FR 40375).

We stated in the CY 2015 PFS proposed rule (79 FR 40375 and 40376) 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 that use of the most current OMB delineations and RUCA codes under the ambulance fee schedule would enhance the accuracy of ambulance fee schedule payments. We solicited comments on our proposal to implement the new OMB delineations and the updated RUCA codes as discussed above beginning in CY 2015, for purposes of payment under the Medicare ambulance fee schedule.

We received four comments from two associations representing ambulance service providers and suppliers and two ambulance suppliers on our proposal to implement the new OMB delineations and the updated RUCA codes for purposes of payment under the Medicare ambulance fee schedule. Those comments are summarized below along with our responses.

Comment: All of the commenters agreed with CMS that it is appropriate to adjust the geographic area designations periodically so that the ambulance fee schedule reflects population shifts.

Response: We appreciate the support of the commenters.

Comment: Commenters expressed concern that the analysis of the proposed modification in the CY 2015 PFS proposed rule did not describe the actual impact of the proposed change because it did not take into account the most recent modifications to the RUCA codes. When these codes are applied, the commenters stated that there would be substantially more ZIP codes that would shift. The commenters estimated that more than 1,500 ZIP codes would shift from rural to urban and about three times the number of ZIP codes identified in the proposed rule would change from urban to rural. The commenters also stated that some ZIP codes would no

longer have super rural status.

Response: The commenters are correct that the analysis published in the CY 2015 PFS proposed rule (see Table 17 (79 FR 40375)) presented the impact of the revised OMB delineations only and did not include the impact of the updated RUCA codes. We did not receive the ZIP code approximation of the 2010 RUCA codes file in time to be included in our analysis in the proposed rule.

We have completed an updated analysis of both the revised OMB delineations and the updated RUCA codes. Based on the latest United States Postal Service (USPS) ZIP code file, there are a total of 42,918 ZIP codes in the U.S. Based on our updated analysis, we have concluded that the geographic designations for approximately 92.02 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. There are more ZIP codes that would change from rural to urban (3,038 or 7.08 percent) than from urban to rural (387 or 0.90 percent). The differences in the data provided in the proposed rule compared to the final rule are due to inclusion of the updated RUCA codes. In general, it is expected that ambulance providers and suppliers in 387 ZIP codes within 41 states, may 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 California has the most ZIP codes changing from urban to rural with a total of 43, or 1.58 percent. Ambulance providers and suppliers in 3,038 ZIP codes within 46 states and Puerto Rico may 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 Pennsylvania has the most ZIP codes changing from rural to urban (293, or 13.06 percent), while West Virginia has the greatest percentage of ZIP codes changing from rural to urban (269 ZIP codes, or 28.74 percent). Our findings are illustrated in Table 47.

TABLE 47: Updated ZIP Codes 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	83	9.72%	8	0.94%	763	89.34%
AR	725	41	5.66%	6	0.83%	678	93.52%
AS	1	0	0.00%	0	0.00%	1	100.00%
AZ	569	21	3.69%	7	1.23%	541	95.08%
CA	2723	94	3.45%	43	1.58%	2586	94.97%
CO	677	4	0.59%	9	1.33%	664	98.08%
CT	445	56	12.58%	0	0.00%	389	87.42%
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	856	71	8.29%	2	0.23%	783	91.47%
FL	1513	105	6.94%	9	0.59%	1399	92.47%
FM	4	0	0.00%	0	0.00%	4	100.00%
GA	1032	101	9.79%	4	0.39%	927	89.83%
GU	21	0	0.00%	0	0.00%	21	100.00%
HI	143	9	6.29%	3	2.10%	131	91.61%
IA	1080	42	3.89%	3	0.28%	1035	95.83%
ID	335	3	0.90%	0	0.00%	332	99.10%
IL	1628	159	9.77%	7	0.43%	1462	89.80%
IN	1000	110	11.00%	7	0.70%	883	88.30%
KY	1030	81	7.86%	5	0.49%	944	91.65%
LA	739	101	13.67%	1	0.14%	637	86.20%
MA	751	14	1.86%	6	0.80%	731	97.34%
MD	630	84	13.33%	0	0.00%	546	86.67%
ME	505	19	3.76%	12	2.38%	474	93.86%
MH	2	0	0.00%	0	0.00%	2	100.00%
MI	1185	63	5.32%	13	1.10%	1109	93.59%
MN	1043	47	4.51%	7	0.67%	989	94.82%
MP	3	0	0.00%	0	0.00%	3	100.00%
MS	541	36	6.65%	1	0.18%	504	93.16%
MT	411	0	0.00%	3	0.73%	408	99.27%
NC	1101	163	14.80%	6	0.54%	932	84.65%
ND	419	2	0.48%	0	0.00%	417	99.52%
NE	632	7	1.11%	6	0.95%	619	97.94%
NH	292	6	2.05%	2	0.68%	284	97.26%
NJ	747	1	0.13%	2	0.27%	744	99.60%
NM	438	4	0.91%	2	0.46%	432	98.63%
NV	257	4	1.56%	2	0.78%	251	97.67%

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	180	8.01%	42	1.87%	2024	90.12%
OH	1487	80	5.38%	34	2.29%	1373	92.33%
OK	791	23	2.91%	7	0.88%	761	96.21%
OR	495	26	5.25%	9	1.82%	460	92.93%
PA	2244	293	13.06%	38	1.69%	1913	85.25%
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	543	91	16.76%	2	0.37%	450	82.87%
SD	418	0	0.00%	1	0.24%	417	99.76%
TN	814	82	10.07%	12	1.47%	720	88.45%
TX	2726	155	5.69%	32	1.17%	2539	93.14%
UT	359	2	0.56%	0	0.00%	357	99.44%
VA	1277	147	11.51%	13	1.02%	1117	87.47%
VI	16	0	0.00%	0	0.00%	16	100.00%
VT	309	15	4.85%	0	0.00%	294	95.15%
WA	744	29	3.90%	6	0.81%	709	95.30%
WI	919	66	7.18%	5	0.54%	848	92.27%
WK	711	16	2.25%	5	0.70%	690	97.05%
WM	342	4	1.17%	3	0.88%	335	97.95%
WV	936	269	28.74%	0	0.00%	667	71.26%
WY	198	0	0.00%	1	0.51%	197	99.49%
TOTALS	**42918**	**3038**	**7.08%**	**387**	**0.90%**	**39493**	**92.02%**

* 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).

As discussed above, in the CY 2015 PFS proposed rule (79 FR 40374), we proposed to designate as rural those census tracts that fall in RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. However, upon further analysis, we have determined that it is not feasible to implement this proposal. Payment under the ambulance fee schedule is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We

believe that payment for all ambulance transportation services at the ZIP code level provides a consistent payment system. Therefore, such census tracts were not considered rural areas in the updated analysis set forth above.

For more detail on the impact of these changes, in addition to Table 47, the following files are available through the Internet on the AFS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html: ZIP codes by state that changed from urban to rural, ZIP codes by state that changed from rural to urban, list of ZIP codes with RUCA code designations, and a complete list of ZIP codes identifying their designation as super rural, rural or urban.

As reflected in Table 47, our findings are generally consistent with the commenters' findings that more than 1,500 ZIP codes would change from rural to urban (our updated analysis indicates that 3,038 ZIP codes are changing), and that about three times the number of ZIP codes identified in the proposed rule (100) would change from urban to rural (our updated analysis indicates 387 ZIP codes are changing).

As we stated in the proposed rule (79 FR 40374), 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.

Comment: One commenter suggested that we delay the implementation of the adjustment until CY 2016 to allow CMS sufficient time to publish the changes in rural and urban status and allow all interested parties to provide comments on the proposal. In addition to delaying implementation, the commenter suggested implementing a 4-year transition that would phase-in the payment reduction over a specified period for those ZIP codes losing rural status.

Other commenters requested that the implementation of the geographic adjustments

outlined in the proposed rule be delayed until such time as the data is available to complete a full and accurate analysis of the ZIP codes affected and the financial impact to industry. Absent such a delay, the commenters stated that the final rule must clarify, in a complete and transparent manner, the accuracy of the analysis used in the proposed rule.

Response: We believe that ambulance providers and suppliers had sufficient notice of and opportunity to comment on the proposed adoption of the revised OMB delineations and the updated RUCA codes under the ambulance fee schedule, and thus we do not believe a delay in implementation is warranted. In the proposed rule, we proposed to adopt the revised OMB delineations as set forth in OMB Bulletin No. 13-01 and the updated RUCA codes for purposes of payment under the ambulance fee schedule consistent with the policy we implemented in CY 2007 (see the CY 2007 PFS final rule (71 FR 69713 through 69716)). We explained in the proposed rule that the adoption of the revised OMB delineations and updated RUCA codes would affect the urban/rural designation of certain areas, and thus would affect whether transports in certain areas would be eligible for rural adjustments under the ambulance fee schedule. In addition, OMB Bulletin No. 13-01was available on February 28, 2013, and contained additional information regarding the changes in OMB geographic area delineations. As discussed above, the ZIP code analysis set forth in the proposed rule reflected the impact of the revised OMB delineations. The 2010 RUCA codes and definitions were available on December 31, 2013 on the U.S. Department of Agriculture's Economic Research Service's website, which provided ambulance providers and suppliers with additional information regarding changes to the level of rurality in census tracts. Furthermore, section 1834(l) requires that we use the most recent modification of the Goldsmith Modification to determine rural census tracts for purposes of certain rural add-ons, and our established policy, as set forth in §414.605, is that rural areas include rural census tracts as determined under the most recent

version of the Goldsmith modification.

As discussed above and in the CY 2015 PFS proposed rule, 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. We believe that it is important to use the most current OMB delineations and RUCA codes available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts. Because we believe the revised OMB delineations and updated RUCA codes more accurately identify urban and rural areas and enhance the accuracy of the Medicare ambulance fee schedule, we do not believe a delay in implementation or a transition period would be appropriate. Areas that lose their rural status and become urban have become urban because of recent population shifts. We believe it is important to base payment on the most accurate and up-to-date geographic area delineations available. Furthermore, we believe a delay would disadvantage the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes.

Finally, given the relatively small percentage of ZIP codes affected by the revised OMB delineations and updated RUCA codes (a total of 3,425 ZIP codes changing their urban/rural status out of 42,918 ZIP codes, or 7.98 percent), we do not believe that a delay is warranted. As commenters requested, we have included in Table 47 our updated analysis of the impact of adopting the revised OMB delineations and the updated RUCA codes.

Comment: One commenter recommended that if any ZIP codes would lose their super rural status as a result of the proposed adoption of the revised OMB delineations and the updated RUCA codes, then CMS should grandfather the current super rural ZIP codes. Another

commenter stated that the ambulance providers must have verification from CMS that the super rural ZIP codes will not be affected by the changes described in the proposed rule in advance of their implementation in the final rule.

Response: As we stated previously, the adoption of the OMB's revised delineations and the updated RUCA codes will have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas will lose their status upon implementation of the revised OMB delineations and the updated RUCA codes. Current areas designated as super rural areas will continue to be eligible for the super rural bonus.

After consideration of the public comments received, and for the reasons discussed above, we are finalizing our proposals to adopt, 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 RUCA codes for purposes of payment under the ambulance fee schedule. As we proposed, using the updated RUCA codes definitions, we will continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas. However, as discussed above, we are not finalizing our proposal to designate as rural those census tracts that fall within RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. Finally, as discussed above, 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.

C. Clinical Laboratory Fee Schedule

In the CY 2014 PFS final rule with comment period (78 FR 74440 through 74445, 74820), we finalized a process under which we would reexamine the payment amounts for test codes on the Clinical Laboratory Fee Schedule (CLFS) for possible payment revision based on technological changes beginning with the CY 2015 proposed rule, and we codified this process at §414.511. After we finalized this process, the Congress enacted the PAMA. Section 216 of

the PAMA creates new section 1834A of the Act, which requires us to implement a new Medicare payment system for clinical diagnostic laboratory tests based on private payor rates. Section 216 of the PAMA also rescinds the statutory authority in section 1833(h)(2)(A)(i) of the Act for adjustments based on technological changes for tests furnished on or after April 1, 2014 (PAMA's enactment date). As a result of these provisions, we did not propose any revisions to payment amounts for test codes on the CLFS based on technological changes, and we proposed to remove §414.511.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to remove §414.511. In addition, we will establish through rulemaking the parameters for the collection of private payor rate information and other requirements to implement section 216 of the PAMA.

D. Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinics (RHC) and Federally Qualified Health Center (FQHC) Visits

1. Background

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) furnish physicians' services; services and supplies "incident to" the services of physicians: nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse. (For additional information on coverage requirements for services furnished in RHCs and FQHCs, see Chapter 13 of the CMS Benefit Policy Manual.)

In the May 2, 2014 final rule with comment period entitled "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" (79 FR 25436), we removed the regulatory requirements that NPs, PAs, CNMs, CSWs, and CPs furnishing services in a RHC must be employees of the RHC. RHCs are now allowed to contract with NPs, PAs, CNMs, CSWs, and CPs, as long as at least one NP or PA is employed by the RHC, as required under clause (iii) in the first sentence of the flush material following subparagraph (K) of section 1861(aa)(2) of the Act.

Services furnished in RHCs and FQHCs by nurses, medical assistants, and other auxiliary personnel are considered "incident to" a RHC or FQHC visit furnished by a RHC or FQHC practitioner. Sections 405.2413(a)(6), 405.2415(a)(6), and 405.2452(a)(6) currently state that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the

RHC or FQHC. Since there is no separate benefit under Medicare law that specifically authorizes payment to nurses, medical assistants, and other auxiliary personnel for their professional services, they cannot bill the program directly and receive payment for their services, and can only be remunerated when furnishing services to Medicare patients in an "incident to" capacity.

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, we proposed to revise §405.2413(a)(5), §405.2415(a)(5) and §405.2452(a)(5) and delete §405.2413(a)(6), §405.2415(a)(6) and §405.2452(a)(6) to remove the requirement that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC, in order to allow nurses, medical assistants, and other auxiliary personnel to furnish "incident to" services under contract in RHCs and FQHCs. We believe that removing the requirements will provide RHCs and FQHCs with additional flexibility without adversely impacting the quality or continuity of care.

We received 23 comments on our proposal. The following is a summary of the comments received.

Comment: Most commenters were strongly in favor of removing these employment requirements. Several commenters stated that this flexibility will assist RHCs and FQHCs in increasing access to care, enable them to recruit highly qualified health professionals, and fill temporary staffing voids without adversely impacting the quality of care. Some commenters expressed concerns about maintaining professional standards, and others were concerned about the potential loss of benefits for contracted staff.

A few commenters stated that they support removal of the employment requirement, provided that RHC and FQHC auxiliary personnel are held to the same high professional standards for the quality of care, regardless of whether they are working under contract or as

employees. Commenters also added that all members of a physician-led health care team should be enabled to perform medical interventions that they are capable of performing according to their education, training, licensure, and experience.

Response: The proposal to remove the requirement that auxiliary workers in RHCs and FQHCs be employees of the RHC or FQHC does not change either their professional standards of care or their scope of practice. Nurses, medical assistants, and other auxiliary personnel are expected to maintain their professional standards of care and furnish services in adherence to their scope of practice, regardless of whether they are employed or contracted by the RHC or FQHC.

Comment: Some commenters stated that although they understand the need for greater staffing flexibility, they were concerned about the potential loss of benefit packages to individuals that are contracted and not employed. The commenters questioned whether the issue was investigated or vetted, and how RHCs and FQHCs would compensate for this loss of compensation for individuals providing incident to services under contract rather than as an employee.

Response: We appreciate the concern that these commenters raised regarding the potential loss of benefit packages for contracted individuals; however, we do not regulate employment agreements or benefit packages for individuals working at RHCs and FQHCs.

After consideration of the public comments, we are finalizing this provision as proposed.

E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models

1. Background and Statutory Authority

Section 3021 of the Affordable Care Act amended the Social Security Act to include a new section 1115A, which established the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A tasks the Innovation Center with testing innovative payment and service delivery models that could reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

Evaluations will typically include quantitative and qualitative methods to assess the impact of the model on quality of care and health care expenditures. To comply with the statutory requirement to evaluate all models conducted under section 1115A of the Act, we will conduct rigorous quantitative analyses of the impact of the model test on health care expenditures, as well as an assessment of measures of the quality of care furnished under the model test. Evaluations will also include qualitative analyses to capture the qualitative differences between model participants, and to form the context within which to interpret the quantitative findings. Through the qualitative analyses, we will assess the experiences and perceptions of model participants, providers, and individuals affected by the model.

In the evaluations we use advanced statistical methods to measure effectiveness. Our methods are intended to provide results that meet a high standard of evidence, even when randomization is not feasible. To successfully carry out evaluations of Innovation Center models, we must be able to determine specifically which individuals are receiving services from or are the subject of the intervention being tested by the entity participating in the model test. Identification of such individuals is necessary for a variety of purposes, including the construction of control groups against which model performance can be compared. In addition,

to determine whether the observed impacts are due to the model being tested and not due to differences between the intervention and comparison groups, our evaluations will have to account for potential confounding factors at the individual level, which will require the ability to identify every individual associated with the model test, control or comparison groups, and the details of the intervention at the individual level.

Evaluations will need to consider such factors as outcomes, clinical quality, adverse effects, access, utilization, patient and provider satisfaction, sustainability, potential for the model to be applied on a broader scale, and total cost of care. Individuals receiving services from or who are the subjects of the intervention will be compared to clinically, socio-demographically, and geographically similar matched individuals along various process, outcome, and patient-reported measures. Research questions in a typical evaluation will include, but are not limited to, the following:

- Clinical Quality:

++ Did the model improve or have a negative impact on clinical process measures, such as adherence to evidence-based guidelines? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on clinical outcome measures, such as mortality rates, and the incidence and prevalence of chronic conditions? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on access to care? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on care coordination among providers? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on medication management? If so, how, how much, and for which individuals?

- Patient Experience:

++ Did the model improve or have a negative impact on patient-provider communication? If so, how, how much, and for which individuals?

++ Did the model improve or have a negative impact on patient experiences of care, quality of life, or functional status? If so, how, how much, and for which individuals?

- Utilization/Expenditures:

++ Did the model result in decreased utilization of emergency department visits, hospitalizations, and readmissions? If so how, how much, and for which individuals?

++ Did the model result in increased utilization of physician or pharmacy services? If so how, how much, and for which individuals?

++ Did the model result in decreased total cost of care? Were changes in total costs of care driven by changes in utilization for specific types of settings or health care services? What specific aspects of the model led to these changes? Were any savings due to improper cost-shifting to the Medicaid program?

To carry out this research we must have access to patient records not generally available to us. As such, we proposed to exercise our authority in section 1115A(b)(4)(B) of the Act to establish requirements for states and other entities participating in the testing of past, present, and future models under section 1115A of the Act to collect and report information that we have determined is necessary to monitor and evaluate such models. Thus, we proposed to require model participants, and providers and suppliers working under the models operated by such participants, to produce such individually identifiable health information and such other information as the Secretary identifies as being necessary to conduct the statutorily mandated research described above. Such research will include the monitoring and evaluation of such models. Further, we view engagement with other payers, both public and private, as a critical

driver of the success of these models. CMS programs constitute only a share of any provider's revenue. Therefore, efforts to improve quality and reduce cost are more likely to be successful if efforts are aligned across payers. Section 1115A of the Act specifically allows the Secretary of Health and Human Services to consider, in selecting which models to choose for testing, "whether the model demonstrates effective linkage with other public sector or private sector payers." Multi-payer models, such as but not limited to the Comprehensive Primary Care model, will conduct quality measurement across all patients regardless of payer in order to maximize alignment and increase efficiency. Construction of multi-payer quality measures requires the ability to identify all individuals subject to the model test regardless of payer. In addition, section 1115A also permits the Secretary to consider models that allow states to test and evaluate systems of all-payer payment reform for the medical care of residents of the state, including dual eligible individuals. Under the State Innovation Model (SIM), the Innovation Center is testing the ability for state governments to accelerate transformation. The premise of the SIM initiative is to support Governor-sponsored, multi-payer models that are focused on public and private sector collaboration to transform the state's payment and delivery system. States have policy and regulatory authorities, as well as ongoing relationships with private payers, health plans, and providers that can accelerate delivery system reform. SIM models must impact the preponderance of care in the state and are expected to work with public and private payers to create multi-payer alignment. The evaluation of SIM will include all populations and payers involved in the state initiative, which in many cases includes private payers. The absence of identifiable data from private payers would result in considerable limitations on the level of evaluation conducted. Therefore, under this authority, we also proposed to require the submission of identifiable health and utilization information for patients of private payers treated by providers/suppliers participating in the testing of a model under section 1115A of the Act

when an explicit purpose of the model test is to engage private sector payers. This regulation will provide clear legal authority for Health Insurance Portability and Accountability Act (HIPAA) Covered Entities to disclose any required protected health information. Identifiable data submitted by entities participating in the testing of models under section 1115A of the Act will meet CMS Acceptable Risks Safeguards (ARS) guidelines. When data is expected to be exchanged over the internet, such exchange will also meet all E-Gov requirements. In accordance with the requirements of the Privacy Act of 1974, upon receipt by CMS or its contractors, these data will be covered under a CMS-established system of records (System No. 09–70–0591), which serves as the Master system for all demonstrations, evaluations, and research studies administered by the Innovation Center. These data will be stored until the evaluation is complete and all necessary policy deliberations have been finalized.

2. Provisions of the Proposed Regulations

Wherever possible, evaluations will make use of claims, assessment, and enrollment data available through CMS' existing administrative systems. However, evaluations will generally also need to include additional data not available through existing CMS administrative systems. As such, depending on the particular project, CMS or its contractor will require the production of the minimum data necessary to carry out the statutorily mandated research work described in section E.1. of this final rule with comment period. Such data may include the identities of the patients served under the model, relevant clinical details about the services furnished and outcomes achieved, and any confounding factors that might influence the evaluation results achieved through the delivery of such services. For illustrative purposes, below are examples of some of the types of information that could be required to carry out an evaluation, and for which the evaluator would need patient-level identifiers.

- Utilization data not otherwise available through existing Centers for Medicare & Medicaid Services (CMS) systems.
- Beneficiary, patient, participant, family, and provider experiences.
- Beneficiary, patient, participant, and provider rosters with identifiers that allow linkages across time and datasets.
- Beneficiary, patient, participant, and family socio-demographic and ethnic characteristics.
- Care management details, such as details regarding the provision of services, payments or goods to beneficiaries, patients, participants, families, or other providers.
- Beneficiary, patient, and participant functional status and assessment data.
- Beneficiary, patient, and participant health behaviors.
- Clinical data, such as, but not limited to lab values and information from EHRs.
- Beneficiary, patient, participant quality data not otherwise available through claims.
- Other data relevant to identified outcomes—for example, participant employment status, participant educational degrees pursued/achieved, and income.

We invited public comment on this proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act.

In addition, we proposed a new subpart K in part 403 to implement section 1115A of the Act.

The following is a summary of the comments we received regarding our proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act.

Comment: Commenters consistently recognized the need to evaluate Innovation Center models as an important component of the effort to test new payment and service delivery models. Further, several commenters supported the need for rigorous evaluations that include control groups. One commenter further recommended the Innovation Center make the aggregated de-identified data from evaluations available to external researchers. Although supportive of the need to evaluate Innovation Center models, several commenters stated the Innovation Center had not sufficiently justified the need for individually identifiable patient information, and suggested aggregate or de-identified data should be sufficient. One commenter suggested the submission of performance rates, patient outcomes information, and/or composite scores for participating providers instead of individual patient-level data. The commenter further stated that CMS should not have access to proprietary patient-level data in registries. Some of the commenters stated CMS should publish its evaluation methodologies and solicit feedback from independent research experts as to the need for patient-level data.

Response: We appreciate the commenters' support for rigorous evaluations, and understand the desire for access to the aggregate de-identified data from these evaluations. We always make our data available in accordance with applicable law, HHS and CMS policies, and, where relevant, the availability of funding. Such laws include HIPAA, the Privacy Act, the Trade Secrets Act and the Freedom of Information Act. With respect to comments recommending the use of aggregate or de-identified data instead of individually identifiable data, as we discussed in the preamble of the proposed rule, we believe individually identifiable data is necessary. As noted in this final rule with comment and in the preamble of our proposed rule, evaluations will need to consider such factors as outcomes, clinical quality, adverse effects, access, utilization, patient and provider satisfaction, sustainability, potential for the model to be applied on a broader scale, and total cost of care. Furthermore, individuals receiving services

from or who are the subjects of the intervention will be compared to clinically, socio-demographically, and geographically similar matched individuals along various process, outcome, and patient-reported measures. Many of these assessments will require person-level data. We will make use of aggregate information on system performance through the use of provider submitted aggregate performance rates for selected measures, patient outcomes information, and/or composite scores. However, without the ability to identify specifically which beneficiaries are receiving services as a result of the model, the evaluation analyses could include individuals not even subject to the intervention, and therefore, there would be a very real possibility that positive impacts of the model may be diluted and unobservable. While aggregate data could be limited to the target population, identification of which individuals are within the target population of the model, are receiving items and services under the model, or are subject to the interventions being tested under the model will also allow the evaluators to construct matched comparison groups that look as similar as possible to the intervention group. The absence of a well-matched comparison group, which can only be achieved when individually identifiable characteristics are known, could result in impact estimates that are inaccurate because these impact estimates could be due to differences between the intervention group and the comparison group and not the intervention itself. Further, while we will need to know the identifiers of beneficiaries that are the subject of the model test, the submission of other patient-level data from proprietary registries would be limited to data necessary to conduct a credible evaluation. Data on individuals are also needed to assess differential impacts among subgroups of beneficiaries to identify who benefits most from the intervention. We agree it is important to seek expert opinion on the structure of our assessment methods, and so these models are developed in concert with and run through our evaluation contractors, which are independent research firms and academic institutions. Where needed, these contractors also reach out to

technical expert panels for added guidance. As a result, the design and implementation of these assessments are informed by those with expertise in health services research, economics, statistics, program evaluation, epidemiology, and public health.

Comment: Although generally supportive of the need for rigorous evaluations, some commenters worried that any requirement to provide individually identifiable data for monitoring and/or assessment purposes would impose an undue administrative burden on model participants, and could lead to the need to submit large (and, potentially, overbroad) amounts of individually identifiable patient-level data. A few commenters suggested that the Innovation Center should first look to other federal government sources before requesting data from model participants. Several commenters noted that it would be costly to produce patient-level data for models with a multi-payer focus, and others stated additional payment should be made to model participants to offset the cost of data reporting. Further, it was suggested that CMS estimate the potential burden and cost on physicians and other providers, and if found to be burdensome, give physicians the right to opt out of producing information that may not be available due to cost limitations or other administrative barriers, such as barriers to producing data stored in electronic health records.

Response: We agree that our determination of what data are necessary to evaluate a model should be made taking into consideration the burden and cost associated with collecting and reporting such data, including the complexities associated with abstracting data from electronic health records. We further agree that in making such determinations, we should take advantage of all existing federal data systems, wherever possible so that we may minimize the amount of data that we must obtain from model participants. Our regulation will only require that model participants collect and report data as is necessary for monitoring or evaluation; thus, if we do not need the data, we would not seek to collect it from model participants.

Reimbursement may be considered for future models, but if adopted, any such reimbursement, and any conditions for such reimbursement, would be prominently noted in the solicitation or modifications to model agreements. To the extent feasible, we also agree that it is important for potential model participants to understand the data collection requirements before the model begins, so that they may take these requirements into consideration. We do not agree, though, that model participants should be given the opportunity to opt out of producing the required information, as this would undermine the evaluation and skew results.

With respect to the specific data needed for evaluation purposes, in many models, the evaluators will be able to determine who the individuals are that are the subjects of the model test without the need to obtain identifiers from the model participants. In those cases, there is a beneficiary-specific payment under the model and the evaluator can use our existing administrative data systems to identify which beneficiaries are in the model. In this last example, although we may not need to obtain the identifiers, we may still need to obtain other person-level data, such as clinical information. In other models, where a specific beneficiary-level payment is not being made, the evaluation contractor will not have an ability to identify the individuals targeted by the model participants. In this latter circumstance, the participants will need to provide the identifiers that would then be used by the evaluator to link to existing administrative data systems. Although the exact data needs will vary by model, in some cases we would determine that only the identifiers (such as, but not limited to, the Medicare Health Insurance Claim number) are required. In other circumstances, it is possible the evaluators will need other data, such as clinical data not otherwise available in claims to properly account for severity of disease. In this manner we will limit data demands, and the attendant costs, to the data necessary to accomplish the required monitoring and assessment.

Comment: Some commenters stated the requirement could result in requests for data from providers tangentially involved in an Innovation Center project to report any data the agency decides it needs. A few commenters further stated the Innovation Center should ensure that all participating entities seek patient authorizations to use their records for the purpose of evaluating the model.

Response: Section 1115A(b)(4) of the Act authorizes us to establish requirements for "States and other entities participating in the testing of models" to collect and report data necessary for monitoring and evaluating the models. Our regulation, therefore, establishes this requirement only with respect to model participants. We consider model participants to include any party that has agreed to participate in, or that receives payment from us under, a model we are testing. In response to the comment suggesting that the Innovation Center ensure that all participating entities seek patient authorizations to use their records for the purpose of evaluating the model, we decline to impose such a requirement in implementing section 1115A(b)(4) of the Act, and we refer such entities to their own legal counsel for advice on whether any form of consent would be required by other applicable law.

Comment: Some commenters stated the Innovation Center should publish and be transparent about what the exact data reporting and collection requirements would be so that participants would have notice of what data they would be required to collect. Commenters stated that without a notice and comment period as part of the model test, there will be no opportunity for stakeholders to weigh in with their perspective of what constitutes the minimum necessary information to achieve the evaluation goals. A few commenters stated the Innovation Center should first determine the specific data elements that are required for evaluation purposes for the existing programs and this information should be shared with participants who should, at minimum, be given an opportunity to provide comment on the required inputs for which they

will be responsible as part of the evaluation. These commenters also stated the Innovation Center should develop such requirements in advance of the program start for participants to allow them an opportunity to provide feedback and weigh the information as part of their decision to participate in the model.

Response: We agree it is important to restrict data requests to the data necessary to conduct credible monitoring and evaluation. We frequently provide stakeholders the opportunity to weigh in on what data they believe would be necessary to evaluate a model, generally through webinars that we conduct during model development and implementation. Further, in order for potential model participants to understand the likely data reporting requirements, to the extent feasible, these requirements are incorporated into the solicitation process. However, we decline to adopt a requirement to undertake a notice and comment process as part of our determination of what data are necessary for monitoring or evaluation because we believe the process already in place allows for model participant feedback. We also disagree with commenters who recommend that we make the determination and specify the particular data elements that will be required for monitoring and evaluation prior to the start of the model. It is not always possible at that early stage of the model to know precisely what data elements will be necessary. However, we will strive to provide as much relevant detail as possible about data collection and reporting requirements in any solicitation process and in any ongoing communications with potential participants, and we will continue to take any comments received into account in determining our data needs.

Comment: A few commenters stated that CMS has not provided sufficient assurances that providers, in responding to these data requests, would be protected or deemed to be in compliance with the HIPAA requirements for the use and disclosure of protected health information (PHI). These commenters stated the Innovation Center reference to requiring

reporting of individually identifiable patient-level data raises significant privacy concerns for providers who would be required to report such data. These commenters stated HIPAA requires that providers limit the use and disclosure of personal health information to the minimum necessary to accomplish the intended purpose of the disclosure. These commenters stated the Innovation Center requests for such data must be in compliance with providers' HIPAA obligations. As such, some commenters stated CMS should work with the Office for Civil Rights (OCR) to ensure providers reporting data as part of an evaluation are doing so consistent with their HIPAA obligations. These commenters stated it is HHS's Office for Civil Rights (OCR) – not CMS – that ultimately determines whether a particular provider is properly compliant and not subject to penalties. These same commenters suggested that the Innovation Center should work with OCR to issue OCR guidance stating that providers reporting data as part of an evaluation are doing so consistent with their HIPAA obligations. Some commenters stated CMS should consider the necessary data elements on a program-by-program basis rather than establishing a blanket approval, or at minimum limit the scope of the approved data requirements and uses, and should provide clear instructions and other educational resources to ensure that collection and reporting of the data complies with the HIPAA Privacy and Security rules.

Response: We appreciate the concerns expressed about compliance with the HIPAA requirements and the recommendation to work with OCR. However, we respectfully disagree that sufficient assurances have not been provided. The disclosure would be required by a regulation, so it would be "required by law" under HIPAA. See 45 CFR 164.512(a) and the definition of "required by law" at 45 CFR 164.103. A HIPAA covered entity is permitted to disclose protected health information as required by law under these provisions so long as the disclosure complies with and is limited to the relevant requirements of the law. A separate

minimum data necessary determination is not required under the HIPAA Privacy Rule for required by law disclosures under 45 CFR 164.512(a). See 45 CFR 164.502(b) (2). Although a separate minimum data necessary determination is not required, as a policy matter and consistent with the statutory authority under 1115A(b) (4), CMS will only require that data we determine is necessary for evaluation and monitoring of Innovation Center models.

Comment: Several commenters stated that collection of beneficiary-level health information raises significant security concerns. Although supportive of sharing relevant and medically necessary patient information, one commenter raised a particular concern that some data could be sensitive information related to mental health or substance abuse. Some commenters stated CMS should adopt safeguards against inappropriate use or disclosure of patient identifiable data.

Response: We agree that it is critical to abide by rigorous security standards, and we take patient privacy seriously. As CMMI is part of Fee-for-Service Medicare, a Health Care Component that is subject to the HIPAA requirements, providers' and suppliers' data will generally be subject to the same HIPAA privacy and security requirements as that data was subject to in the hands of the providers and suppliers from which it came. Furthermore, if stored in a manner searchable by individual identifiers, it will also be subject to the Privacy Act of 1974.

As HIPAA Business Associates, this data will be equally well protected when held by one of our evaluation contractors. In addition, the disclosure of substance abuse records will, where applicable, also be subject to the Part 2 regulations.

Comment: One commenter stated CMS should not use these data for purposes other than those articulated in the proposed rule, and that the assessments should comply with the applicable statutory requirements, meaning that: (1) The assessments should take into account

all of the factors outlined under section 1115A(b)(4) of the Act (that is, quality of care, including patient-level outcomes and patient-centeredness criteria); (2) the assessments should be made publicly available; and (3) CMS should pursue notice-and-comment rulemaking before any of the CMS demonstrations are expanded based on these assessments, as required by section 1115A(c) of the Act.

Response: We agree that evaluations should assess quality of care, and the patient-de-identified results should be made publicly available, as required by section 1115A(b)(4) of the Act. We would pursue model expansion according to the terms of the statute.

After consideration of the public comments we received, we are finalizing our proposal to mandate the production of the individually identifiable information necessary to conduct the statutorily mandated research under section 1115A of the Act. We are accepting the recommendations made by commenters to minimize participant burden, seek input from providers, and use independent researchers. In addition, we are finalizing our proposal to add a new subpart K in part 403 to implement section 1115A of the Act without modification.

F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

The CY 2015 proposed rule (79 FR 40378 through 40380), section III.F., included discussion of a proposal to modify the existing process used by the Medicare Administrative Contractors (MACs) in developing local coverage determinations (LCDs) for clinical diagnostic laboratory tests. Briefly, the proposal would have expedited the timeline for LCD development for clinical diagnostic laboratory test LCDs by reducing the calendar days for some of the steps and by making optional or eliminating other steps within the current process. A detailed discussion of the proposal is available in section III.F. of the CY 2015 PFS Proposed Rule.

We would like to thank the numerous public commenters for their time in submitting thoughtful comments to the agency on this issue. Comments were received from individual members of the public, insurers, drug manufacturers, medical specialty societies, laboratory groups and individual laboratories. The commenters focused their comments on the following issues: the proposal to reduce the draft LCD public comment period to 30 days; the proposal for a meeting of the Carrier Advisory Committee to be optional; the proposal to remove the requirement for a public meeting; and the proposal to eliminate the 45-day notice period prior to final LCDs becoming effective. In addition, commenters were concerned about the proposed changes in light of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), titled "Improving Medicare Policies for Clinical Diagnostic Laboratory Tests."

The comments received have given the agency much to consider prior to moving forward with any changes to the LCD process; therefore, we will not finalize any changes to the LCD process in this final rule. We will explore the possibility of future notice-and-comment rulemaking on this issue.

G. 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 would 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. Regulations governing the requirements and procedures for private contracts appear at 42 CFR part 405, subpart D.

a. Opt-out Determinations (§405.450)

The private contracting regulation at §405.450 describes certain opt-out determinations made by Medicare, and the process that physicians, practitioners, and beneficiaries may use to appeal those determinations. Section 405.450(a) describes the process available for physicians or practitioners to appeal Medicare enrollment determinations related to opting out of the program, and §405.450(b) describes the process available to challenge payment determinations related to claims for services furnished by physicians who have opted out. Both provisions refer to §405.803, the Part B claims appeals process that was in place at the time the opt-out regulations were issued (November 2, 1998). When those regulations were issued, a process for a physician or practitioner to appeal enrollment related decisions had not been implemented in regulation. Thus, to ensure an appeals process was available to physicians and practitioners for opt-out related issues, we chose to utilize the existing claims appeals process in §405.803 for both enrollment and claims related appeals.

In May 16, 2012 **Federal Register** (77 FR 29002), we published a final rule entitled "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction." In that final rule, we deleted the provisions relating to initial determinations, appeals, and reopenings of Medicare Part A and Part B claims, and relating to determinations and appeals regarding an individual's entitlement to benefits under Medicare Part A and Part B, which were contained in part 405, subparts G and H (including §405.803) because these provisions were obsolete and had been replaced by the regulations at part 405, subpart I. We inadvertently neglected to revise the cross-reference in §405.450(a) and (b) of the private contracting regulations to direct appeals of opt-out determinations through the current appeal process. However, it is important to note that our policy regarding the appeal of opt-out determinations did not change when the appeal regulations at part 405, subpart I were finalized.

The procedures set forth in current part 498 establish the appeals procedures regarding decisions made by Medicare that affect enrollment in the program. We believe this process, and not the appeal process in part 405, subpart I, is the appropriate channel for physicians and practitioners to challenge an enrollment related opt-out decision made by Medicare. There are now two different sets of appeal regulations for initial determinations; and the appeal of enrollment related opt-out determinations is more like the types of determinations now addressed under part 498 than those under part 405, subpart I. Specifically, the appeal process under part 405, subpart I focuses on reviews of determinations regarding beneficiary entitlement to Medicare and claims for benefits for particular services. The appeal process under part 498 is focused on the review of determinations regarding the participation or enrollment status of providers and suppliers. Enrollment related opt-out determinations involve only the status of particular physician or practitioners under Medicare, and do not involve beneficiary eligibility or

claims for specific services. As such, the appeal process under part 498 is better suited for the review of enrollment related opt-out determinations.

However, we do not believe the enrollment appeals process established in part 498 is the appropriate mechanism for challenging payment decisions on claims for services furnished by a physician and practitioner who has opted out of the program. Appeals for such claims should continue to follow the appeals procedures now set forth in part 405 subpart I.

b. Definitions, Requirements of the Opt Out Affidavit, Effects of Opting Out of Medicare, Application to Medicare Advantage Contracts (§§405.400, 405.420(e), 405.425(a), and 405.455)

Section 405.400 sets forth certain definitions for purposes of the private contracting regulations. Among the defined terms is "Emergency care services" which means services furnished to an individual for treatment of an "emergency medical condition" as that term is defined in §422.2. The cross-referenced regulation at §422.2 included within the definition of emergency care services was deleted on June 29, 2000 (65 FR 40314) and at that time we inadvertently neglected to revise that cross-reference. The cross-reference within the definition of emergency care services should have been amended at that time to cite the definition of "emergency services" in §424.101.

The private contracting regulations at §405.420(e), §405.425(a) and §405.455 all use the term Medicare+Choice when referring to Part C plans. However, we no longer use the term Medicare+Choice when referring to Part C plans; instead the plans are referred to as Medicare Advantage plans. When part 422 of the regulations was updated on January 28, 2005 (70 FR 4741), we inadvertently neglected to revise §405.420(e), §405.425(a) and §405.455 to replace the term Medicare+Choice with Medicare Advantage plan.

2. Provisions of the Proposed Regulation

For the reasons discussed above, we proposed that a determination described in §405.450(a) (relating to the status of opt-out or private contracts) is an initial determination for purposes of §498.3(b), and a physician or practitioner who is dissatisfied with a Medicare determination under §405.450(a) may utilize the enrollment appeals process currently available for providers and suppliers in part 498. In addition, we proposed that a determination described in §405.450(b) (that payment cannot be made to a beneficiary for services furnished by a physician or practitioner who has opted out) is an initial determination for the purposes of §405.924 and may be challenged through the existing claims appeals procedures in part 405 subpart I. Accordingly, we proposed that the cross reference to §405.803 in §405.450(a) be replaced with a cross reference to §498.3(b). We also proposed that the cross reference to §405.803 in §405.450(b) be replaced with a cross reference to §405.924. We also proposed corresponding edits to §498.3(b) and §405.924 to note that the determinations under §405.450(a) and (b), respectively, are initial determinations.

For the reasons discussed above, we also proposed that the definition of Emergency care services at §405.400 be revised to cite the definition of Emergency services in §424.101 and that all references to Medicare+Choice in §405.420(e), §405.425(a) and §405.455 be replaced with the term "Medicare Advantage."

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

Comment: Commenters requested that physicians and practitioners be allowed to opt out of Medicare indefinitely instead of submitting a new affidavit every 2 years.

Response: These comments are outside the scope of this rule as they are not related to the proposed changes to the opt-out regulations. Nevertheless, we note that section 1802(b)(3)(B)(ii) of the Act specifies that the opt-out affidavit must provide that the "physician or practitioner will not submit any claim under this title for any item or service provided to any

medicare beneficiary… during the 2-year period beginning on the date the affidavit is signed." As such, the longest interval for which an opt-out can be effective is 2 years. We have no authority to modify that statutory requirement.

Because we did not receive any comments on our proposals, we are finalizing the rule as proposed.

H. Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

1. Background

In accordance with section 1842(b)(6) of the Act, no payment under Medicare Part B may be made to anyone other than to the beneficiary to whom a service was furnished or to the physician or other person who furnished the service. However, there are certain limited exceptions to this general prohibition. For example, section 1842(b)(6)(D) of the Act describes an exception for substitute physician billing arrangements, which states that "payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the [Medicare Administrative contractor (MAC)] for such services includes the second physician's unique identifier . . . and indicates that the claim meets the requirements of this

subparagraph for payment to the first physician." Section 1842(b)(6) of the Act is self-implementing and we have not interpreted the statutory provisions through regulations.

In practice, section 1842(b)(6)(D) of the Act generally allows for two types of substitute physician billing arrangements: (1) an informal reciprocal arrangement where doctor A substitutes for doctor B on an occasional basis and doctor B substitutes for doctor A on an occasional basis; and (2) an arrangement where the services of the substitute physician are paid for on a per diem basis or according to the amount of time worked. Substitute physicians in the second type of arrangement are sometimes referred to as "locum tenens" physicians. It is our understanding that locum tenens physicians are substitute physicians who often do not have a practice of their own, are geographically mobile, and work on an as-needed basis as independent contractors. They are utilized by physician practices, hospitals, and health care entities enrolled in Part B as Medicare suppliers to cover for physicians who are absent for reasons such as illness, pregnancy, vacation, or continuing medical education. Also, we have heard anecdotally that locum tenens physicians are used to fill staffing needs (for example, in physician shortage areas) or, on a temporary basis, to replace physicians who have permanently left a medical group or employer.

We are concerned about the operational and program integrity issues that result from the use of substitute physicians to fill staffing needs or to replace a physician who has permanently left a medical group or employer. For example, although our Medicare enrollment rules require physicians and physician groups or organizations to notify us promptly of any enrollment changes (including reassignment changes) (see §424.516(d)), processing delays or miscommunication between the departing physician and his or her former medical group or employer regarding which party would report the change to Medicare could result in the Provider Transaction Access Number (PTAN) that links the departed physician and his or her former

medical group remaining "open" or "attached" for a period of time. During such period, both the departed physician and the departed physician's former medical group might bill Medicare under the departed physician's National Provider Identifier (NPI) for furnished services. This could occur where a substitute physician is furnishing services in place of the departed physician in the departed physician's former medical group, while the departed physician is also furnishing services to beneficiaries following departure from the former group. Operationally, either or both types of claims could be rejected or denied, even though the claims filed by the departed physician were billed appropriately. Moreover, the continued use of a departed physician's NPI to bill for services furnished to beneficiaries by a substitute physician raises program integrity issues, particularly if the departed physician is unaware of his or her former medical group or employer's actions.

Finally, as noted above, section 1842(b)(6)(D)(iv) of the Act requires that the claim form submitted to the MAC include the substitute physician's unique identifier. Currently, the unique identifier used to identify a physician is the physician's NPI. Prior to the implementation of the NPI, the Unique Physician Identification Number (UPIN) was used. Because a substitute physician's NPI is not captured on the CMS-1500 claim form or on the appropriate electronic claim, physicians and other entities that furnish services to beneficiaries through the use of a substitute physician are required to enter a modifier on the CMS-1500 claim form or on the appropriate electronic claim indicating that the services were furnished by a substitute physician; and to keep a record of each service provided by the substitute physician, associated with the substitute physician's UPIN or NPI; and to make this record available to the MAC upon request. (See Medicare Claims Processing Manual (Pub. 100-4), Chapter 1, Sections 30.2.10 and 30.2.11) However, having a NPI or UPIN does not necessarily mean that the substitute physician is enrolled in the Medicare program. Without being enrolled in Medicare, we do not know whether

the substitute physician has the proper credentials to furnish the services being billed under section 1842(b)(6)(D) of the Act or if the substitute physician is sanctioned or excluded from Medicare. The importance of enrollment and the resulting transparency afforded the Medicare program and its beneficiaries was recognized by the Congress when it included in the Affordable Care Act a requirement that physicians and other eligible non-physician practitioners (NPPs) enroll in the Medicare program if they wish to order or refer certain items or services for Medicare beneficiaries. This includes those physicians and other eligible NPPs who do not and will not submit claims to a Medicare contractor for the services they furnish. We solicited comments regarding how to achieve similar transparency in the context of substitute physician billing arrangements for the identity of the individual actually furnishing the service to a beneficiary.

2. Analysis of Comments

To help inform our decision whether and, if so, how to address the issues discussed in section III.H.1., and whether to adopt regulations interpreting section 1842(b)(6)(D) of the Act, we solicited comments on the policy for substitute physician billing arrangements. We noted that any regulations would be proposed in a future rulemaking with opportunity for public comment. Through this solicitation, we hoped to understand better current industry practices for the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians might have on beneficiary access to physician services.

We received a few comments on the issues raised in this solicitation. We thank the commenters for their input, and we will carefully consider their comments in any future rulemaking on this subject.

I. Reports of Payments or Other Transfers of Value to Covered Recipients

1. Background

In the February 8, 2013 **Federal Register** (78 FR 9458), we published the "Transparency Reports and Reporting of Physician Ownership or Investment Interests" final rule which implemented section 1128G of the Social Security Act ("Act"), as added by section 6002 of the Affordable Care Act. Under section 1128G(a)(1) of the Act, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis information about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Section 1128G(a)(2) of the Act requires applicable manufacturers and applicable group purchasing organizations (GPOs) to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. The implementing regulations are at 42 CFR part 402, subpart A, and part 403, subpart I. We have organized these reporting requirements under the "Open Payments" program.

The Open Payments program creates transparency around the nature and extent of relationships that exist between drug, device, biologicals and medical supply manufacturers, and physicians and teaching hospitals (covered recipients and physician owner or investors). The implementing regulations, which describe procedures for applicable manufacturers and applicable GPOs to submit electronic reports detailing payments or other transfers of value and ownership or investment interests provided to covered recipients and physician owners or investors, are codified at §403.908.

Since the publication and implementation of the February 8, 2013 final rule, various stakeholders have provided feedback to CMS regarding certain aspects of these reporting requirements. Specifically, §403.904(g)(1) excludes the reporting of payments associated with certain continuing education events, and §403.904(c)(8) requires reporting of the marketed name for drugs and biologicals but makes reporting the marketed name of devices or medical supplies optional. We proposed a change to §403.904(g) to correct an unintended consequence of the current regulatory text. Additionally, at §403.904(c)(8), we proposed to make the reporting requirements consistent by requiring the reporting of the marketed name for drugs, devices, biologicals, or medical supplies which are associated with a payment or other transfer of value.

Additionally, at §403.902, we proposed to remove the definition of a "covered device" because we believe it is duplicative of the definition of "covered drug, device, biological or medical supply" which is codified in the same section. We also proposed to require the reporting of the following distinct forms of payment: stock; stock option; or any other ownership interests specified in §403.904(d)(3) to collect more specific data regarding the forms of payment.

2. Continuing Education Exclusion (§403.904(g)(1))

In the February 8, 2013 final rule, many commenters recommended that accredited or certified continuing education payments to speakers should not be reported because there are safeguards already in place, and they are not direct payments to a covered recipient. In the final rule preamble, we noted that "industry support for accredited or certified continuing education is a unique relationship" (78 FR 9492). Section 403.904(g)(1) states that payments or other transfers of value provided as compensation for speaking at a continuing education program need not be reported if the following three conditions are met:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following

organizations: the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the American Dental Association's Continuing Education Recognition Program (ADA CERP); the American Medical Association (AMA); or the American Osteopathic Association (AOA).

- The applicable manufacturer does not pay the covered recipient speaker directly.
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

Since the implementation of §403.904(g)(1), other accrediting organizations have requested that payments made to speakers at their events also be exempted from reporting. These organizations have stated that they follow the same accreditation standards as the organizations specified in §403.904(g)(1)(i). Other stakeholders have recommended that the exemption be removed in its entirety stating removal of the exclusion will allow for consistent reporting for compensation provided to physician speakers at all continuing education events, as well as transparency regarding compensation paid to physician speakers. Many stakeholders raised concerns that the reporting requirements are inconsistent because certain continuing education payments are reportable, while others are not. CMS' apparent endorsement or support to organizations sponsoring continuing education events was an unintended consequence of the final rule.

After consideration of these comments, we proposed to remove the language in §403.904(g) in its entirety, in part because it is redundant with the exclusion in §403.904(i)(1). That provision excludes indirect payments or other transfers of value where the applicable manufacturer is "unaware" of, that is, "does not know," the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under §403.904(i)(1). This approach is consistent with our discussion in the preamble to the final rule, in which we explained that if an applicable manufacturer conveys "full discretion" to the continuing education provider, those payments are outside the scope of the rule (78 FR 9492). In contrast, for example, when an applicable manufacturer conditions its financial sponsorship of a continuing education event on the participation of particular covered recipients, or pays a covered recipient directly for speaking at such an event, those payments are subject to disclosure.

We considered two alternative approaches to address this issue. First, we explored expanding the list of organizations in §403.904(g)(1)(i) by name; however, we believe that this approach might imply CMS's endorsement of the named continuing education providers over others. Second, we considered expansion of the organizations in §403.904(g)(1)(i) by articulating accreditation or certification standards that would allow a CME program to qualify for the exclusion. This approach is not easily implemented because it would require evaluating both the language of the standards, as well as the enforcement of the standards of any organization professing to meet the criteria. We solicited comments on both alternatives presented, including commenters' suggestions about what standards, if any, CMS should incorporate.

The following is summary of the comments we received regarding both alternatives presented, and what standards, if any, CMS should incorporate.

Comment: We received numerous comments addressing our proposal to remove the

exclusion for compensation for speaking at a continuing education program. Some comments were in support to remove the exclusion stating it is an important step toward ensuring transparency. Supporting comments also agreed removing the exclusion will level the playing field with the medical education community. Numerous commenters questioned our proposal to remove the exclusion for compensation for speaking at a continuing education program. Commenters provided background regarding accrediting continuing education organizations stating that creating continuing education accreditation standards is a function of professional self-regulation and additional government regulation is not necessary.

Many commenters recommend modifying the indirect payment exclusion currently at § 403.904(i)(1) to specify a continuing education indirect payment should be excluded if the manufacturer did not know the identity of the covered recipient before providing the payment to a third party, such as a continuing education organization. This differs from the current indirect payment exclusion language which states the payment is excluded if the manufacturer did not know the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. Commenters stated it is not practical for a manufacturer to not know the identity of a physician speaker receiving compensation for speaking at a continuing education event during the reporting year or by the end of the second quarter of the following reporting year because manufacturers could learn the identities of physician speakers through brochures, programs and other publications. Therefore, commenters assert that the indirect payment exclusion is not applicable to exclude compensation provided to physicians at a continuing education event and recommend the indirect payment exclusion is modified to accommodate indirect payments provided to a physician covered recipient through a continuing medical education organization.

Additionally, commenters suggested an alternative approach where CMS would adopt

established criteria, such as the Standards for Commercial Support: Standards to Ensure Independence in CME Activities, in order to have payments provided to physicians at continuing education events excluded. Similar criteria suggested by commenters to modify the exclusion were: does not pay covered speakers or attendees directly, does not select covered recipient speakers or provide a third party with a distinct, identifiable set of individuals to be considered as speakers or attendees for the continuing education program, and does not control the continuing education program content.

Response: We appreciate commenters support to remove the exclusion for compensation for speaking at a continuing education program. We appreciate the comments stating that continuing medical education accrediting organizations is a function of professional self-regulation. We believe creating consistent reporting requirements for all continuing education events, by removing the language in §403.904(g) in its entirety, will provide enhanced regulatory clarity for stakeholders. Manufacturers reporting compensation paid to physician speakers may opt to distinguish if the payment was provided at an accredited or certified continuing education program versus an unaccredited or non-certified continuing education program by selecting the appropriate nature of payment category at §403.904(e).

We understand commenters concern regarding learning the identity of the physician during the reporting year or by the end of the second quarter of the following reporting year. In the situation of an applicable manufacturer providing an indirect payment through a continuing education organization and learning the identity of the physician covered recipient in the allotted timeframe (during the reporting year or by the end of the second quarter of the following reporting year) the indirect payment would not meet the criteria of the indirect payment exclusion and would need to be reported. However, payments or other transfers of value, including payments made to physician covered recipients for purposes of attending or speaking

at continuing education events, which do not meet the definition of an indirect payment, as defined at §403.902, are not reportable. For example, if an applicable manufacturer or applicable GPO provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to a covered recipient, the applicable manufacturer or applicable GPO is not required to report the payment or other transfer of value. The payment is not reportable regardless if the applicable manufacturer or applicable GPO learns the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year because the payment or other transfer of value did not meet the definition of an indirect payment. This approach is also consistent with our statement at (78 FR 9490), where we explained that "if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute 'indirect payments' because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians." Therefore, because such payments are not indirect payments, we do not need to create an additional exclusion specific to continuing education indirect payments by modifying the indirect payment exclusion at §403.904(i)(1).

Comment: Many commenters interpreted the removal of physician speaker compensation at continuing education events would also remove the reporting exclusion for attendees at accredited or certified continuing education events whose fees have been subsidized through the continuing medical education organization by an applicable manufacturers.

Response: We did not intend to remove the exclusion regarding subsidized fees provided to physician attendees by manufacturers at continuing education events. However, we intend for

physician speaker compensation and physician attendees fees which have been subsidized through the continuing medical education organization by an applicable manufacturer to be reported unless the payment meets the indirect payment exclusion at §403.904(i)(1). This allows for consistent reporting for physician attendees and speakers at continuing education events. We will provide sub-regulatory guidance specifying tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported. However, if a manufacturer does instruct, direct, or otherwise cause the subsidized tuition fee for a continuing education event to go to a specific physician attendee, the payment will not be excluded, since the indirect payment exclusion only applies if the manufacturer did not know the identity of the physician attendee.

Comment: Many commenters interpreted the proposed removal of§403.904(g) to expand the exclusion to account for continuing education programs accredited or certified for nurses, optometrists, pharmacists, and others.

Response: We appreciate the comments, but the removal of§403.904(g) was not intended to expand the exclusion. The intent is to allow for consistent reporting for compensation provided to physician speakers at all continuing education events, as well as transparency regarding compensation paid to physician speakers.

Comment: A few commenters requested CMS provide clear and realistic timeframes regarding payments related to continuing education events to allow manufacturers to provide sponsor notice as it considers proposals to eliminate the current CME exclusion.

Response: We agree with commenters that manufacturers may need additional time to comply with reporting requirements; therefore, we are finalizing data collection requirements that would begin January 1, 2016 according to this final rule for applicable manufacturers.

3. Reporting of Marketed Name (§403.904(c)(8))

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to ‘‘marketing, education, or research’’ of a particular covered drug, device, biological, or medical supply. Section 403.904(c)(8)(i) requires applicable manufacturers to report the marketed name for each drug or biological related to a payment or other transfer of value. At §403.904(c)(8)(ii), we require an applicable manufacturer of devices or medical supplies to report one of the following: the marketed name; product category; or therapeutic area. In the February 8, 2013, final rule, we provided applicable manufactures with flexibility when it was determined that the marketed name for all devices and medical supplies may not be useful for the general audience. We did not define product categories or therapeutic areas in §403.904(c). However, since implementation of the February 8, 2013 final rule and the development of the Open Payments system, we have determined that aligning the reporting requirements for marketed name across drugs, biologics, devices and medical supplies will make the data fields consistent within the system, and also enhance consumer’s use of the data.

Accordingly, we proposed to revise §403.904(c)(8) to require applicable manufacturers to report the marketed name for all covered drugs, devices, biologicals or medical supplies. We believe this would facilitate consistent reporting for the consumers and researchers using the data displayed publicly on the Open Payments. Manufacturers would still have the option to report product category or therapeutic area, in addition to reporting the market name, for devices and medical supplies.

Comment: We received a few comments regarding revising reporting requirements at §403.904(c)(8). These comments mainly stated that the marketed name for a device or medical supply is not useful for the public because the public is not familiar with device or medical supply marketed names. We also received a few comments that supported requiring the

reporting of marketed name for devices and medical supplies. Supporting commenters believe that reporting marketed name for all products will allow the public (including researchers and consumers) to search the data via the Open Payments public website for a specific device or medical supply. Commenters also stated that reporting marketed name for non-covered products is not required by the statute and therefore manufacturers should not be required to report marketed names for non-covered products. Additionally, some comments indicated reporting marketed name for devices and medical supplies for research payments is not practical because there is not a marketed name for every device or medical supply associated with research payments; rather there may only be a connection to an associated research study. A few commenters addressed that manufacturers will have an increased burden to modify reporting systems to accommodate reporting marketed name for devices and medical supplies.

Response: We appreciate the comments supporting our proposed revisions requiring reporting marketed name for devices and medical supplies. We have finalized a modified approach to accommodate concerns regarding reporting related covered drug, device, biological or medical supply information. We agree manufacturers should not be required to report marketed names for non-covered products; therefore, we are finalizing the proposal that reporting marketed names for non-covered drugs, devices, biologicals, or medical supplies will continue to be optional. We also agree a payment or other transfer of value associated with a research payment regarding a device or medical supply may not have a marketed name. Therefore, we are finalizing the proposal that manufacturers will continue to have an option to report either a device or medical supply marketed name, therapeutic area or product category when reporting research payments.

After consideration of comments received, we agree that displaying therapeutic areas or product categories are useful for the public reviewing data on the Open Payments public website

because the public is not familiar with marketed names for devices and medical supplies. We agree therapeutic areas and products categories are more recognizable by the public. Yet, reporting marketed names for all covered products is necessary to achieve consistent reporting and to have the ability to aggregate all payments or other transfers of value associated with a specific device or medical supply. Therefore to achieve consistent reporting by manufacturers, we will require manufacturers to report marketed name and therapeutic area or product category for all covered drugs, devices, biologicals or medical supplies. We also agree with commenters that complying with this reporting requirement will require a change in manufacturers' reporting systems; therefore, data collection for this reporting requirement would begin January 1, 2016.

4. Reporting of Stock, Stock Option, or any other Ownership Interest

Section 403.904(d)(3) requires the reporting of stock, stock option, or any other ownership interest. We proposed to require applicable manufacturers to report such payments as distinct categories. This will enable us to collect more specific data regarding the forms of payment made by applicable manufacturers. After issuing the February 8, 2013 final rule and the development of the Open Payments system, we determined that this specificity will increase the ease of data aggregation within the system, and also enhance consumer's use of the data. We solicited comments on the extent to which users of this data set find this disaggregation to be useful, and whether this change presents operational or other issues on the part of applicable manufacturers.

The following is summary of the comments we received regarding the extent to which users of this data set find this disaggregation to be useful, requiring reporting of marketed name for covered devices and medical supplies, and whether this change presents operational or other issues on the part of applicable manufacturers.

Comment: Commenters agreed that requiring reporting of stock, stock option or any

other ownership interest in distinct categories is useful.

Response: We agree the disaggregation of reporting stock, stock option or any other ownership interest in distinct categories. Therefore, we have finalized this provision as proposed, which requires reporting stock, stock option, or any other ownership interest form of payment or other transfer of value in distinct categories.

J. Physician Compare Website

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop 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.

CMS 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.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that began no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance 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.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must 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 eligible professionals 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 and 78 FR 74450). 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.). In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary determines appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the MIPPA.

Under section 10331(f) of the Affordable Care Act, we are required to submit a report to the Congress by January 1, 2015, on Physician Compare development, and include 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. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

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 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. On June 27, 2013, we launched a full redesign of Physician Compare bringing significant improvements including a complete overhaul of the underlying database and a new Intelligent Search feature, addressing two of our stakeholders' primary critiques of the site – the accuracy and currency of the database and the limitations of the search function – and considerably improving website functionality and usability. Provider Enrollment, Chain, and Ownership System (PECOS), as the sole source of verified Medicare professional information, is the primary source of administrative information on Physician Compare. With the redesign, however, we incorporated the use of Medicare Fee-For-Service claims information to verify the information in PECOS to help ensure only the most current and accurate information is included on the site. For example, claims information is used to determine which of the active and approved practice locations in PECOS are where the professional is currently providing services. Claims information helps confirm that only the most current group practice affiliations are included on the site. Our use of claims also helps ensure that we are posting on Physician Compare the most current and accurate information available about the professionals for Medicare consumers.

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, including the additional labeling, improvements to the "Is this you?" link, the reordering of the search results, the Intelligent Search functionality, the use of claims data to verify

professionals' demographic information, denoting board certified physicians with contextual text, and explanations and disclaimers about each of the federal quality reporting programs included on the website. Commenters also noted an 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 provided suggestions for future Physician Compare enhancements. A few commenters suggested continued improvements to the Intelligent Search functionality to better find health care professionals other than physicians and additional specialty labels for Advanced Practice Registered Nurses (APRNs) and allied health professionals.

Response: We appreciate the commenters' feedback and the continued support for the Physician Compare website. 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 also appreciate the recommendations regarding other health care professionals, and we will evaluate these recommendations for potential future inclusion. Also, we are continually working to improve and enhance the Intelligent Search functionality.

Comment: Some commenters expressed concerns about the accuracy of data such as demographic information, specialty classification, and hospital affiliation. Several commenters urged CMS to address these concerns prior to posting additional quality measure performance information on the website. Other commenters requested we implement a streamlined process by which professionals can confirm or correct their information in a timely manner. One commenter urged CMS to ensure that updates made in PECOS are reflected on Physician Compare within 30 days, while another commenter cautioned against using PECOS for updating information. Several commenters suggested continuing to work with stakeholders, particularly

health care professionals, and/or providing educational material regarding how to keep data current to ensure the accuracy of the website.

Response: We appreciate the commenters' feedback regarding concerns over the accuracy of the 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 on Physician Compare is generated from PECOS, as well as Fee-For-Service (FFS) claims, and it is therefore 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. 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 Medicare Administrative Contractor (MAC) and available in the PECOS data pulled for Physician Compare. This time is necessary for data verification but unfortunately results in a delay updating information. We are continually working to find ways to minimize this delay.

To update information not found in PECOS, such as hospital affiliation and foreign language, professionals and group practices should contact the Physician Compare support team directly at PhysicianCompare@Westat.com. Information regarding how to keep your information current can also be found on the Physician Compare Initiative page on CMS.gov

(http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/).

Although we appreciate the concerns raised around the PECOS data included on Physician Compare, it is necessary to continue the use of the PECOS data as it is the sole, verified source of Medicare information. However, we are aware of its limitations. For these reasons, we have instituted the use of claims information and are continuing to work to find ways to further improve the data. The data are significantly better today than they were prior to the 2013 redesign and continues to improve. 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.

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, languages spoken, and American Board of Medical Specialties (ABMS) board certification information. In addition, for group practices, users can also view group practice names, specialties, practice locations, Medicare assignment status, and affiliated professionals.

We post on the website the names of individual EPs who satisfactorily report under PQRS, as well as those EPs who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. Physician Compare contains a link to a downloadable database of all information on Physician Compare (https://data.medicare.gov/data/physician-compare), including information on this quality program participation. 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. We proposed (79 FR 40386) to continue to include this information annually in the year following the year it is reported (for example, 2015 PQRS reporting will be included on the website in 2016). We did not receive any comments on this proposal. We are finalizing this proposal at this time, and therefore, will include satisfactory 2015 PQRS reporters on the website in 2016. The eRx Incentive Program ends in 2014 so those data will not be available in 2015 or beyond.

With the Physician Compare redesign, we added a quality programs section to each group practice profile page in order to indicate which group practices are satisfactorily reporting in the Group Practice Reporting Option (GPRO) under PQRS or are successful electronic prescribers under the eRx Incentive Program. We have also included a notation and check mark for individuals that successfully participate in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act. We proposed (79 FR 40386) to continue to include this information annually in the year following the year it is reported (for example, 2015 data will be included on the website in 2016).

We did not receive any comments regarding our proposal regarding this PQRS GPRO. We are finalizing the proposal to include a notation for satisfactory PQRS GPRO reporters. As noted above, the eRx Incentive Program is ending in 2014, and therefore, there will not be data for this program in 2015 or beyond. We did receive comments regarding including a notation for individuals that successfully participate in the Medicare EHR Incentive Program.

Comment: Two commenters urged CMS to reconsider its decision to publicly report participation in the Medicare EHR Incentive Program due to ongoing issues related to the program--including unresolved challenges related to vendor certification delays, concerns about the relevancy to consumers, and limited ability to implement core measures. One commenter suggested including a disclaimer next to the indicator explaining these barriers and clarifying

that successful participation in the EHR Incentive Program is only one of various ways to demonstrate an investment in higher quality care.

Response: We appreciate the commenters' feedback, and we will take the suggestions provided regarding a disclaimer into consideration for possible future enhancements. We also appreciate the concerns raised about the program, specifically around vendor certification and core measures. However, despite those potential limitations, a number of professionals and groups are successfully taking part at this time and we believe it is important to continue to recognize them. Also, consumers find this information interesting and helpful. This is only one of multiple quality programs included on Physician Compare that we find important to highlight. As a result, we are going to finalize our proposal to continue including an indicator for participation in the EHR Incentive Program on the website.

We previously finalized a decision to publicly report the names of those EPs who report the 2014 PQRS Cardiovascular Prevention measures group in support of Million Hearts on Physician Compare in 2015, by including a check mark in the quality programs section of the profile page (78 FR 74450). We proposed (79 FR 40386) to also continue to include this information annually in the year following the year it is reported (for example, 2015 data will be included on Physician Compare in 2016).

Comment: Some commenters supported our proposal to publicly report and include an indicator for EPs who report the 2015 PQRS Cardiovascular Prevention measures group in support of Million Hearts. Commenters noted that Million Hearts is an important initiative for supporting cardiovascular health.

Response: We appreciate the commenters' support. We agree that Million Hearts is an important initiative that is improving outcomes for cardiovascular health. However, we are finalizing the removal of the Cardiovascular Prevention measure group from the PQRS program

given that the two cholesterol control measures included in the measure group are no longer clinically relevant, and therefore, the measure group no longer meets the necessary threshold for PQRS of six measures and will no longer be available for reporting under the program. With the removal of the 2 cholesterol control measures, the remaining measures from the original Cardiovascular Prevention measure group are:

- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use.
- Controlling High Blood Pressure.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

All of these measures are available as individual measures under PQRS. Given that the Cardiovascular Prevention measure group is being eliminated from the PQRS, but that the remaining measures identified above will be available for individual reporting, we are modifying our final policy with regard to our proposal to support Million Hearts on Physician Compare. Specifically, we are finalizing that any EP that satisfactorily reports all four of the individual measures noted above will receive a green check mark indicating support for Million Hearts. A key strategy of the Million Hearts initiative is to reduce the number of heart attacks and strokes, and the program has found that reporting these quality measures is a first step toward performance improvement. We are committed to supporting this initiative, and even though the measure group is no longer available under PQRS, we think it is important to continue recognizing those individual EPs who are reporting these quality measures as individual measures. Even though the individual measures require that a potentially higher number of patients are reported on – 50 percent of patients that meet the sample requirements versus just 20 patients for the measure group – we believe this does not increase burden on reporters because as

currently available claims data show, significantly more EPs are already reporting these measures as individual PQRS measures versus as part of the Cardiovascular Prevention measures group. Ensuring these professionals are recognized for reporting these measures is important in ensuring we are continuing support for this important program despite the measure group no longer being available for reporting.

Finally, we will also indicate with a green check mark those individuals who have earned the 2014 PQRS Maintenance of Certification Incentive (Additional Incentive) on the website in 2015 (78 FR 74450).

Comment: Several commenters supported publicly reporting earners of the PQRS Maintenance of Certification (MOC) program Additional Incentive, as well as ABMS Board Certification data, while other commenters are concerned that ABMS data are not complete or only include some specialists. Multiple commenters suggested including other Boards' certifications and MOC programs, contextual certification process information, and the certifying Board's identification.

Response: We appreciate the commenters' feedback and support for including ABMS and PQRS MOC information on Physician Compare. We also understand the concerns that not all specialties are presented by the ABMS data and will review the recommendations made to include additional certification and MOC program information on the website for possible inclusion in the future.

We continue to implement our plan for a phased approach to public reporting performance information on Physician Compare. The first phase of this plan was finalized with the CY 2012 PFS final rule with comment period (76 FR 73419-73420), where we established that PQRS GPRO measures collected through the GPRO Web Interface for 2012 would be publicly reported on Physician Compare. The plan was expanded with the CY 2013 PFS final

rule with comment period (77 FR 69166), where we established that the specific GPRO Web Interface measures that would be posted on Physician Compare would include the PQRS GPRO measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD), and we noted that we would report composite measures for these measure groups in 2014, if technically feasible.[6] The 2012 PQRS GPRO measures were publicly reported on Physician Compare in February 2014. Data reported in 2013 on the GPRO DM and GPRO CAD measures and composites collected via the GPRO Web Interface that meet the minimum sample size of 20 patients and prove to be statistically valid and reliable will be publicly reported on Physician Compare in December CY 2014, if technically feasible. 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 group's performance rate on that measure will not be publicly reported. We will only publish on Physician Compare 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.

Measures must be based on reliable and valid data elements to be useful to consumers and thus included on Physician Compare. A reliable data element is consistently measuring the same thing regardless of when or where it is collected, while a valid data element is measuring what it is meant to measure. To address the reliability of performance scores, we will measure the extent to which differences in each quality measure are due to actual differences in clinician performance versus variation that arises from measurement error. Statistically, reliability depends on performance variation for a measure across clinicians ("signal"), the random variation in performance for a measure within a clinician's panel of attributed beneficiaries

[6] By "technically feasible" we mean that there are no operational constraints inhibiting us from moving forward on a given public reporting objective. Operational constraints include delays and/or issues related to data collection which render a set of quality data unavailable in the timeframe necessary for public reporting.

("noise"), and the number of beneficiaries attributed to the clinician. High reliability for a measure suggests that comparisons of relative performance across clinicians are likely to be stable over different performance periods and that the performance of one clinician on the quality measure can confidently be distinguished from another. Potential reliability values range from zero to one, where one (highest possible reliability) means that all variation in the measure's rates is the result of variation in differences in performance, while zero (lowest possible reliability) means that all variation is a result of measurement error. Reliability testing methods included in the CMS Measures Management System Blueprint (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html) include test-retest reliability and analysis of variance (ANOVA). Reliability tests endorsed by the NQF include the beta-binomial model test.

The validity of a measure refers to the ability to record or quantify what it claims to measure. To analyze validity, we can investigate the extent to which each quality measure is correlated with related, previously validated, measures. We can assess both concurrent and predictive validity. Predictive validity is most appropriate for process measures or intermediate outcome measures, in which a cause-and-effect relationship is hypothesized between the measure in question and a validated outcome measure. Therefore, the measure in question is computed first, and the validated measure is computed using data from a later period. To examine concurrent validity, the measure in question and a previously validated measure are computed using contemporaneous data. In this context, the previously validated measure should measure a health outcome related to the outcome of interest.

Comment: Many commenters supported only publishing on Physician Compare those measures that are statistically valid and reliable. Several commenters urged CMS to carefully

assess if all GPRO measure data is sufficiently reliable and valid for public reporting before posting the data. One commenter recommended removing any measures deemed unreliable or inaccurate. One commenter recommended a one-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.

One commenter requested CMS publish the results of validity and reliability studies, as well as the methodology for choosing measures prior to posting on Physician Compare. Another commenter is concerned that measures related to patient behavior, preferences, or abilities do not provide a statistically valid portrayal of a health care professional's performance and should not be published unless the data is appropriately risk adjusted. Several other commenters also strongly urged CMS to move forward with expanding its risk adjustment methodology.

Response: We appreciate the commenters' feedback, and understand the 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 the established standards of reliability and validity 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 are also making changes in light of the concerns about first year measures. We will not publicly post

measures that are in their first year given the concerns raised about their validity, reliability, accuracy, and comparability. After a measure's first year in the program, CMS will evaluate the measure to see if and when the measure is suitable for pubic reporting. Also, we will continue to analyze the measure data to ensure that risk adjustment concerns are taken into consideration. All data are analyzed and reviewed by our Technical Expert Panel (TEP). A summary of the TEP recommendations is made public on the Physician Compare Initiative page (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Informational-Materials.html) when available.

In the November 2011 Medicare Shared Savings Program final rule (76 FR 67948), we noted that because Accountable Care Organization (ACO) providers/suppliers that are EPs are considered to be a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we would publicly report ACO performance on quality measures on Physician Compare in the same way as we report performance on quality measures for PQRS GPRO group practices. Public reporting of performance on these measures is presented at the ACO level only. The first sub-set of ACO measures was also published on the website in February 2014. ACO measures can be viewed by following the link for Accountable Care Organization (ACO) Quality Data on the homepage of the Physician Compare website (http://medicare.gov/physiciancompare/aco/search.html).

As part of our public reporting plan for Physician Compare, in the CY 2013 PFS final rule with comment period (77 FR 69166 and 69167), we also finalized the decision to publicly report Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) data for group practices of 100 or more eligible professionals reporting data in 2013 under the GPRO and for ACOs participating in the Shared Savings Program, if technically feasible. We anticipate posting these data on Physician Compare in late 2014, if available.

We continued to expand our plan for public reporting data on Physician Compare in the CY 2014 PFS final rule with comment period (78 FR 74449). In that final rule we finalized a decision that all measures collected through the GPRO Web Interface for groups of two or more EPs participating in 2014 under the PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program would be available for public reporting in CY 2015. As with all measures we finalized with regard to Physician Compare, these data would include measure performance rates for measures reported that meet the minimum sample size of 20 patients and prove to be statistically valid and reliable. We also finalized a 30-day preview period prior to publication of quality data on Physician Compare. This will allow group practices to view their data as it will appear on Physician Compare before it is publicly reported. We decided that we will detail 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. ACOs will be able to view their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare.

We also finalized a decision to publicly report in CY 2015 on Physician Compare performance on certain measures that group practices report via registries and EHRs in 2014 for the PQRS GPRO (78 FR 74451). Specifically, we finalized making available for public reporting performance on 16 registry measures and 13 EHR measures (78 FR 74451). These measures are consistent with the measures available for public reporting via the Web Interface. We will indicate the mechanism by which these data were collected and only those data deemed statistically comparable, valid, and reliable would be published on the site.

We also finalized publicly reporting patient experience survey-based measures from the CG-CAHPS measures for groups of 100 or more eligible professionals who participate in PQRS

GPRO, regardless of GPRO submission method, and for Shared Savings Program ACOs reporting through the GPRO Web Interface or other CMS-approved tool or interface (78 FR 74452). For 2014 data, we finalized publicly reporting data for the 12 summary survey measures also finalized for groups of 25 to 99 for PQRS reporting requirements (78 FR 74452). These summary survey measures would be available for public reporting group practices of 100 or more EPs participating in PQRS GPRO, as well as group practices of 25 to 99 EPs when collected via any certified CAHPS vendor regardless of PQRS participation, as technically feasible. 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 (78 FR 74452) will be available for public reporting in 2015.

For 2014, we also finalized publicly reporting 2014 PQRS measure data reported by individual EPs in late CY 2015 for individual PQRS quality measures specifically identified in the final rule with comment period, if technically feasible. Specifically, we finalized to make available for public reporting 20 individual measures collected through a registry, EHR, or claims (78 FR 74453-74454). These are measures that are in line with those measures reported by groups via the GPRO Web Interface.

Finally, in support of the HHS-wide Million Hearts Initiative, we finalized a decision to publicly report, no earlier than CY 2015, performance rates on measures in the PQRS Cardiovascular Prevention measures group at the individual EP level for data collected in 2014 for the PQRS (78 FR 74454). See Table 48 for a summary of our final policies for public reporting data on Physician Compare.

TABLE 48: 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, and participants in the EHR Incentive Program.
2012	2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices reporting under PQRS GPRO 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, 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	Expected to be December 2014	WI	Up to 6 DM and 2 CAD measures collected via the GPRO WI for groups of 25 or more EPs and Shared Savings Program ACOs with a minimum sample size of 20 patients. Will include composites for DM and CAD, if feasible.
2013	Expected to be December 2014	WI	Up to 5 CG-CAHPS summary measures for groups of 100 or more EPs reporting under PQRS GPRO via the WI and up to 6 ACO CAHPS summary measures for Shared Savings Program ACOs.
2014	Expected to be 2015	WI, EHR, Registry, Claims	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry, Administrative Claims	All measures reported via the GPRO WI, 13 EHR, and 16 Registry GPRO measures are also available for group practices of 2 or more EPs reporting under PQRS GPRO with a minimum sample size of 20 patients. Also, all Shared Savings Program ACO measures are available for public reporting. Include composites for DM and CAD, if feasible.
2014	Expected to be late 2015	WI, Certified Survey Vendor	Up to 12 CG-CAHPS 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, as well as 6 ACO CAHPS summary measures for Shared Savings Program ACOs reporting through the GPRO Web Interface or other CMS-approved tool or interface.
2014	Expected to be late 2015	Registry, EHR, or Claims	A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through a Registry, EHR, or claims with a minimum sample size of 20 patients.
2014	Expected to be late 2015	Registry	Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of the Million Hearts Initiative with a minimum sample size of 20 patients.

3. Final Policies for Public Data Disclosure on Physician Compare in 2015 and 2016

We are continuing the expansion of public reporting on Physician Compare by making an even broader set of quality measures available for publication 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 (79 FR 40388) to increase the measures available for public reporting in the CY 2015 proposed PFS rule.

Comment: Although multiple commenters supported continuing the phased approach to public reporting of quality data, a number of commenters are concerned with the aggressive timeline for publicly reporting performance data. Several commenters supported a more gradual approach to public reporting to evaluate the public response to data prior to widespread implementation, ensure accuracy, and present data in a format that is easy to understand, meaningful, and actionable for both patients and health care professionals. A few commenters were unsure if CMS conducted analysis of consumer use of the site and urged CMS to do so. Other commenters opposed the extensive expansion until existing website problems are addressed.

Response: We appreciate the commenters' feedback, and we appreciate the concerns raised. However, we believe that public reporting of quality data has been a measured, phased approach which started with the publication of just five 2012 PQRS GPRO measures collected via the Web Interface for 66 group practices and 141 ACOs (76 FR 73417) and continues with a similarly limited set of 2013 PQRS GPRO Web Interface measures (77 FR 69166). We started to build on this plan with the 2014 Physician Fee Schedule (PFS) final rule (78 FR 74446). This rule made additional PQRS GPRO measures available for public reporting, including a subset of measures reported via Registry and EHR, as well as a sub-set of 20 individual EP PQRS

measures. Therefore, the proposals put forth this year are just the next step in the process to realize goals for authorization 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 proposed (79 FR 40388) to expand public reporting of group-level measures by making all 2015 PQRS GPRO measure sets across group reporting mechanisms – GPRO Web Interface, registry, and EHR – available for public reporting on Physician Compare in CY 2016 for groups of 2 or more EPs, as appropriate by reporting mechanism.[7] Similarly, we also proposed that all measures reported by Shared Savings Program ACOs would be available for public reporting on Physician Compare. As with all quality measures proposed for inclusion on Physician Compare, we noted that only measures that prove to be valid, reliable, and accurate upon analysis and review at the conclusion of data collection would be included on the website.

Comment: Commenters were both positive and negative in regard to our proposal to expand the group-level measures available for public reporting to all measures reported under

[7] Tables Q1-Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

2015 PQRS GPRO. Commenters in support of the proposal noted group-level measures are a robust indication of care team quality and helpful to consumers. Some commenters opposed the expansion and cited concerns with the accuracy of current data as well as measure fidelity. One commenter encouraged CMS to ensure that GPRO quality data is accurately labeled and accessible through the group entry only to ensure it is clear what the quality measure represents. One commenter asked for clarification on the availability of the PQRS GPRO Web Interface reporting option for groups of two or more EPs.

Response: We appreciate the commenters' feedback on our proposal to report all 2015 PQRS measures reported via the Web Interface, EHR, and Registry for group practices of 2 or more EPs participating in the PQRS GPRO. As noted, Physician Compare will only publicly report those measures evaluated to be comparable, reliable, and valid. Also, we will continue to work to ensure that measures are labeled accurately and accompanied by explanations that are both true to the measure specifications and accurately understood by health care consumers, while adhering to HHS plain language guidelines. Measure data accuracy is of paramount importance to CMS. The measure data currently available on Physician Compare was previewed by those group practices that currently have 2012 PQRS GPRO data available on Physician Compare prior to publication with no concerns raised regarding accuracy. Since being published, no group practices with GPRO data have raised concerns regarding the accuracy of the measure data available. To confirm, the Web Interface reporting option will remain limited to groups of 25 or more EPs. Smaller groups, groups of 2 to 24 EPs, can report under the PQRS via EHR or Registry. We also clarify that group-level data is only published at the group level – included on the group practice profile page -- on Physician Compare. And, in response to comments that raised concern about measures reported in the first year, we have decided that we

will not publicly report a measure that is in its first year. By first year we mean a measure that is newly available for reporting under PQRS.

We also received comments specifically about EHR measures.

Comment: Commenters were opposed to publicly reporting EHR measures, citing that it is too soon to publicly post performance data from eCQMs without additional work to verify the validity and accuracy of the measure results. One commenter suggested that new quality measures could be piloted by health care professionals prior to requiring their use within a federal program. One commenter strongly encouraged developing a tutorial that allows the public to better understand this data.

Response: We appreciate the commenters' feedback regarding including measures collected via EHRs. Group practices will have the ability to report measures via an EHR prior the 2015 data collection. Therefore, this reporting mechanism will not be in its first year of use at this time. As a result, we do not believe it is too soon to report these quality measures. As noted, only comparable, valid, reliable, and accurate data will be included on Physician Compare. All measures slated for public reporting will be consumer tested to ensure they are accurately understood prior to publication. If concerns surface from this testing, we will evaluate if the requirements for public reporting are not suitably met and if the measure or measures in question should be suppressed and not publicly reported to ensure only those measures that are valid, reliable, and accurate and inform quality choice are included on the site.

Given the value of these group-level data, and the successful publication of such data to date, we are finalizing our proposal to report all 2015 PQRS measures for all reporting options for group practices of 2 or more EPs participating in PQRS GPRO, and all 2015 measures reported by ACOs. Consistent with this final policy, we are making a conforming change to the

regulation at §425.308(e) to provide that all quality measures reported by ACOs will be reported on Physician Compare in the same way as for group practices that report under the PQRS.

We also proposed (79 FR 40389) that measures must meet the public reporting criteria of a minimum sample size of 20 patients.

Comment: Several commenters supported the proposed minimum sample size of 20 patients. However, the majority of commenters believed a patient threshold of 20 is too low to be statistically valid, which commenters claim may result in inaccurate quality scores based on one outlier. Commenters recommended CMS use a higher threshold to ensure validity. Several commenters also urged CMS to test measures and composites with 20 patients and to provide an opportunity for public comment and to review reliability and validity.

Response: We appreciate the commenters' feedback and understand the concerns raised regarding the 20 patient minimum sample size. However, we believe this threshold of 20 patients is a large enough sample to protect patient privacy for reporting on the website, and aligns with the reliability threshold previously finalized for the Value-Based Modifier (VM) (77 FR 69166). As we continue to work to align quality initiatives and minimize reporting burden on physicians and other health care professionals, we are finalizing a patient sample size of 20 patients.

We proposed to include an indicator of which reporting mechanism was used and to only include on the site measures deemed statistically comparable.[8] We received several comments regarding data comparability, generally.

Comment: Some commenters expressed concern with the comparability of measures reported through different reporting mechanisms and requested notation specifying the measure differences. One commenter supported only publicly reporting measures with specifications

[8] 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.

consistent across all reporting mechanisms, while another commenter recommended that CMS group results by the data collection methodology to improve comparability.

Response: Though we understand concerns regarding including measures collected via different mechanisms, CMS is conducting analyses to ensure that these measures align across different reporting mechanisms. This analysis is done on a measure per measure basis. For example, if a measure is reported via claims, then the measure specifications would be aligned with a measure being reported via EHR as long as it stays consistent with the original measure intent. 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. Therefore, we are finalizing our proposal to report data from the available reporting mechanisms and to include a notation indicating which reporting mechanism was used.

We proposed (79 FR 40389) to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, we proposed that not all of these measures necessarily would be included on the Physician Compare profile pages. As we noted, consumer testing has shown profile pages with too much information and/or measures that are not well understood by consumers can negatively impact a consumer's ability to make informed decisions. Our analysis of the collected measure data, along with consumer testing and stakeholder feedback, will determine specifically which measures are published on profile pages on the website. Statistical analyses will ensure the measures included are statistically valid and reliable and comparable across data collection mechanisms. Stakeholder feedback will ensure all measures meet current clinical standards. CMS 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. When measures are finalized significantly in advance of moment they are

collected, it is possible that clinical guidelines can change rendering a measure no longer relevant. Publishing that measure can lead to consumer confusion regarding what best practices their health care professional should be subscribing to.

As we noted in the proposed rule (79 FR 40389), 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, CMS will test with consumers how well they understand each measure under consideration for public reporting. If a measure is not consistently understood and/or if consumers do not understand the relevance of the measure to their health care decision making process, CMS will not include the measure on the Physician Compare profile page as inclusion will not aid informed decision making. Finally, consumer testing will help ensure the measures included on the profile pages are accurately understood and relevant to consumers, thus helping them make informed decisions. This will be done to ensure that the information included on Physician Compare is consumer friendly and consumer focused.

Comment: Several commenters supported the proposal to have all 2015 measures available for download with only a select group of measures on the website. One commenter further emphasized CMS should create consistent formatting with Hospital Compare downloadable files.

Response: We appreciate the commenters' feedback and support for this proposal. We are finalizing the proposal to include all measures in a downloadable file and limiting the measures available on Physician Compare profile pages to those measures that not only meet the requirements of public reporting such as validity, reliability, accuracy, and comparability, but that also are accurately understood and interpreted by consumers as evidenced via consumer

testing. This will ensure that the measures presented on Physician Compare help them make informed health care decisions without overwhelming them with too much information. We will also take into future consideration the recommendation regarding the Hospital Compare file.

We also received comments regarding stakeholder involvement and consumer testing.

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 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. One commenter suggested an opportunity for stakeholder associations to participate in the 30-day measure preview process.

Response: We appreciate the commenters' feedback regarding stakeholder outreach and involvement in Physician Compare. As we 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 also are dedicated to providing opportunities for stakeholders to provide input. We will continue to identify the best ways to accomplish this. We will also review all recommendations provided for future consideration.

Comment: Many commenters supported consumer testing to ensure only meaningful measures are included on the site. One commenter suggested CMS first focus on communicating

validated and meaningful information in a user-friendly way. One commenter urged CMS to consult a broader array of stakeholders during concept testing, while another commenter specified the inclusion of health care professionals. 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 for the information currently on the Physician Compare. One commenter emphasized testing must occur prior to placing these additional measures on the website in late 2016. One commenter believed health care professionals must be aware of what measures will be reported to the Physician Compare website before the reporting period begins.

Response: We appreciate the commenters' feedback. 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. We are continually working to test the information planned for public reporting with consumers. We regularly test the information currently on the website with site users. We are planning concept testing of the measures being finalized in this rule prior to publication in 2016 and we will work to ensure that valid, reliable, and meaningful information is included on the website. This testing ensures that the best information is shared and that it is shared in a way that is correctly interpreted.

We will also engage stakeholders for feedback, including input from the public, consumers, and health care professionals, as appropriate and feasible through such opportunities as Town Halls, Listening Sessions, Open Door Forums, and Webinars. We will review feedback for future consideration. Although we establish in rulemaking the subset of measures available

for posting on the Physician Compare website, at this time, however, it is not possible for us to provide stakeholders with the exact list of measures that will be included on the website prior to our analysis of the reported data to know which measures meet the criteria we specified previously for public reporting.

As is the case for all measures published on Physician Compare, 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 detail 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. ACOs will be able to view their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare.

Comment: Several commenters were in support of the 30-day preview period prior to publication of quality data. Many commenters urged CMS to also allow group practices, ACOs, and EPs the opportunity to correct and/or appeal any errors found in the performance information before it is posted on the website. Several commenters recommended CMS postpone posting information if a group practice or EP files an appeal and flags their demographic data or quality information as problematic. Other commenters noted that a 30-day preview period is insufficient and requested that CMS extend the period to 60 or 90 days. One commenter believed the preview period should match the PQRS committee's measure review timeline of 9 months. Some commenters sought clarification on how CMS plans to notify EPs of the preview period and requested more detail about correcting errors found during the preview period.

Response: We appreciate the commenters' feedback regarding the 30-day preview period for quality measures on Physician Compare. Detailed instructions regarding how to preview measure data, the time frame for the measure preview, and directions for how to address

any concerns or get additional help during this process is shared at the start of the preview period with all groups and individuals that have data to preview. If an error is found in the measure display during this 30-day preview, the directions explain how to contact the Physician Compare team by both phone and e-mail to have concerns addressed. Errors will be corrected prior to publication. If measure data has been collected and the measure has been deemed suitable for pubic reporting, the data will be published. This 30-day period is in line with the preview period provided for other public reporting programs such as Hospital Compare. To date, our experience with this preview period for group practices demonstrates that 30 days is sufficient time to allow for preview to be conducted. It is important that quality data be shared with the public as soon as possible so it is as current and relevant as possible when published. To avoid further delaying this publication we will maintain the 30-day preview period.

Group practices and EPs with available data for public reporting will be informed via email when the preview period is going to take place. Group practices and EPs will be provided instructions for previewing data and information for on how to request help or have questions answered. Additionally, information regarding the preview period will be included on the Physician Compare Initiative page on CMS.gov. As noted, ACOs will preview their data via their ACO Quality Reports, which will be sent at least 30 days before data are publicly reported. There is no preview period for demographic data. These data are currently publicly available. If a group practice or EP has questions about their demographic data, they should contact the Physician Compare support team at PhysicianCompare@Westat.com.

In addition to making all 2015 PQRS GPRO measures available for public reporting, we solicited comment (78 FR 40389) on creating composites using 2015 data and publishing composite scores in 2016 by grouping measures based on the PQRS GPRO measure groups, if technically feasible. We indicated we would analyze the data collected in 2015 and conduct

psychometric and statistical analyses, looking at how the measures best fit together and how accurately they are measuring the composite concept, to create composites for certain PQRS GPRO measure groups, including but not limited to:

- Care Coordination/Patient Safety (CARE) Measures
- Coronary Artery Disease (CAD) Disease Module
- Diabetes Mellitus (DM) Disease Module
- Preventive (PREV) Care Measures

In particular, we would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015. Composite scores have proven to be beneficial in providing consumers a better way to understand quality measure data, as composites provide a more concise, easy to understand picture of physician quality.

Comment: Commenters were both positive and negative in regard to our request for information on publicly reporting composite scores. Some commenters stated composites should only be publicly reported if statistically reliable, risk adjusted, or medically meaningful, and should be scientifically or consumer tested prior to public display. A few commenters also suggested NQF endorsement of individual components and composites before finalizing any composites. Several commenters strongly urged CMS to seek input from relevant specialty societies, measure developers, consumers, and other stakeholders on the construction and display if the composites. A few commenters opposed public reporting of composites, but suggested providing physicians the composite scores confidentially through the QRURs. Several commenters noted concerns about the proposal to create composites given the variability in the methodologies, difficulty validating the results, and use of stand-alone measures developed to be reported individually. One commenter suggested stand-alone measures are preferable to

composites in relatively small and heterogeneous measure sets. A few commenters suggested posting additional information about composite measures on Physician Compare clarifying that composite groups are not readily available at this time for all measure groups. One commenter urged CMS to retain more comprehensive information about the measures within each composite measure in the downloadable file. One commenter does not specifically support the Oncology Composite Score on Physician Compare.

Response: We appreciate the commenters' feedback on this request for information. We will be carefully reviewing all concerns raised and recommendations made as we continue to evaluate options for including composites in future rulemaking. This concept was put forth merely to seek comment and no formal proposal was made, so we are not finalizing any decisions regarding composite scores at this time. However, given that we received feedback from stakeholders indicating such composite scores are desired, we plan to analyze the data once it is collected to establish the best possible composite, which would help consumers use these quality data to make informed health care decisions, and will consider proposing such composites in future rulemaking.

Similar to composite scores, benchmarks are also important to ensuring that the quality data published on Physician Compare are accurately interpreted and appropriately understood. A benchmark will allow consumers to more easily evaluate the information published by providing a point of comparison between groups. We continue to receive requests from all stakeholders, but especially consumers, to add this information to Physician Compare. As a result, we proposed (79 FR 40389) to publicly report on Physician Compare in 2016 benchmarks for 2015 PQRS GPRO data using the same methodology currently used under the Shared Savings Program. This ACO benchmark methodology was previously finalized in the November 2011 Shared Savings Program final rule (76 FR 67898), as amended in the CY 2014 PFS final rule

with comment period (78 FR 74759). Details on this methodology can be found on CMS.gov at http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-QM-Benchmarks.pdf. We proposed to follow this methodology using the 2014 PQRS GPRO data.

We proposed to calculate benchmarks using data at the group practice TIN level for all EPs who have at least 20 cases in the denominator. A benchmark per this methodology is the performance rate a group practice must achieve to earn the corresponding quality points for each measure. Benchmarks would be established for each percentile, starting with the 30th percentile (corresponding to the minimum attainment level) and ending with the 90th percentile (corresponding to the maximum attainment level). A quality scoring point system would then be determined. Quality scoring would be based on the group practice's actual level of performance on each measure. A group practice would earn quality points on a sliding scale based on level of performance: performance below the minimum attainment level (the 30th percentile) for a measure would receive zero points for that measure; performance at or above the 90th percentile of the performance benchmark would earn the maximum points available for the measure. The total points earned for measures in each measure group would be summed and divided by the total points available for that measure group to produce an overall measure group score of the percentage of points earned versus points available. The percentage score for each measure group would be averaged together to generate a final overall quality score for each group practice. The goal of including such benchmarks would be to help consumers see how each group practice performs on each measure, measure group, and overall in relation to other group practices.

Comment: Many commenters supported the use of benchmarks to help consumers make informed health care decisions. However, several commenters did not support the calculation of

an overall quality score, as they believe it will result in the unfair comparison of all group practices. Additional commenters noted that benchmarks using percentiles will be difficult for consumers to understand and encouraged consumer testing to remedy this problem. Some commenters noted appropriate methodology is needed when potential data constraints impact the calculation of benchmarks. Several commenters also asked for clarification on the impact of exception rates on quality scores and how benchmarks will be displayed, noting the risk of arbitrary thresholds potentially exaggerating minor performance differences. A commenter asked for the opportunity to review sample data prior to supporting the proposed methodology, while another noted that benchmarks need to be set prior to the beginning of the new measurement period. One commenter sought clarification on whether the benchmarking methodology would be the same as the methodology applied under the Value-Modifier. Several commenters urged CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. One commenter cautioned the use of benchmarks, noting it can lead to an incomplete and potentially misleading indicator of quality.

Response: We appreciate the commenters' feedback on our proposal to include on Physician Compare a benchmark for 2015 PQRS GPRO measures (and measures reported by individual EPs) measures based on the current Shared Savings Program benchmark methodology. Although we agree benchmarks can add great value for consumers, we understand the many concerns raised. As a result, we have made a decision not to finalize this proposal at this time. We want to be sure to discuss more thoroughly potential benchmarking methodologies with our stakeholders prior to finalizing the proposal. We also want to evaluate other programs' methodologies, including the Value Modifier, to work toward better alignment across programs. We therefore feel it would be best to forego finalizing a methodology at this time in favor of a stronger, potentially better aligned methodology that can be included in future rulemaking.

Understanding the value consumers place on patient experience data and the commitment to reporting these data on Physician Compare, we proposed (79 FR 40390) publicly reporting in CY 2016 patient experience data from 2015 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. The patient experience data available are specifically the CAHPS for PQRS and CAHPS for ACO measures, which include the CG-CAHPS core measures. For group practices, we proposed to make available for public reporting these 12 summary survey measures:

- Getting Timely Care, Appointments, and Information.
- How Well Providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.
- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping You to Take Medication as Directed.
- Stewardship of Patient Resources.

We proposed that these 12 summary survey measures would be available for public reporting for all group practices. For ACOs participating in the Shared Savings Program, we proposed (79 FR 40390) that the patient experience measures that are included in the Patient/Caregiver Experience domain of the Quality Performance Standard under the Shared

Savings Program in 2015 would be available for public reporting in 2016. We would review all quality measures after they are collected to ensure that only those measures deemed valid and reliable are included on the website.

We received a number of comments around our proposals to include CAHPS measures on Physician Compare.

Comment: Several commenters supported our proposal to publicly report CAHPS for PQRS data for all group practices that have met the minimum sample size requirements and collect the data using a certified CMS-approved vendor. One commenter strongly encouraged CMS to make public reporting on patient experience measures mandatory for groups of all sizes and individual EPs. However, a few commenters were concerned with public reporting of CAHPS or other patient experience survey data due to the subjectivity of the surveys or the cost of administering the surveys.

Response: We appreciate the commenters' feedback. At this time reporting of CAHPS measures for PQRS is only available at the group practice level, so we will continue to consider these data for group practices. We understand the concerns raised regarding subjectivity and cost. However, we are confident that CAHPS is a well-tested collection mechanism that produces valid and comparable measures of physician quality based on the extensive testing and work that has been done by the Agency for Healthcare Research and Quality's (AHRQ) and specifically the CAHPS Consortium (for more information visit https://cahps.ahrq.gov/). This work illustrates that these measures are accurate measures of patient experience. Because CAHPS for PQRS can be one part of a group's participation in PQRS and are data greatly desired by consumers, we also believe concerns regarding cost are outweighed. For these reasons, we are finalizing our proposal to make available for public reporting the 12 summary

survey CAHPS measures outlined in this rule on Physician Compare for group practices and ACOs, as appropriate.

Comment: Commenters were generally supportive of the proposal to publicly report 12 summary CAHPS scores; however, some are concerned that several CAHPS summary survey measures cannot accurately capture aspects of care over which an individual physician does not have direct control, such as "Getting Timely Care, Appointments and Information" and "Access to Specialists," and urged CMS to only report these measures on an aggregate, group level. Another commenter is concerned with "Stewardship of Patient Resources" survey measure, noting that it is not a physician's role to manage a patient's pocketbook and that other barriers, apart from costs, can impede access to care.

One commenter supported the creation of benchmarks for CAHPS for PQRS measures, and suggested CMS clarify whether those benchmarks will be the same as the ACO CAHPS measure benchmarks, or whether the benchmarks will be specific to the PQRS program, but calculated using the same methodology.

Response: The CAHPS for PQRS measures are designed to be group-level measures. These data will not be calculated for individual EPs; they will be evaluated at the group practice level. We do appreciate the commenters' feedback regarding concerns over specific measures. One important consideration is that because the CAHPS measures are group-level, they are not attributing aspects of care to an individual EP, as not all aspects of care can be easily attributed to a single professional. Prior to deciding the specific measures that will be publicly reported on Physician Compare, we will ensure the measures meet the reliability and validity requirements set for public reporting and that the measures are understood and accurately interpreted by consumers. If a summary survey measure does not meet these criteria, it will not be publicly

reported on Physician Compare. At this time, we are not adopting any benchmarks for CAHPS for PQRS on Physician Compare.

Comment: One commenter sought additional information on how CAHPS for PQRS performance measures will be displayed. Another commenter suggested that public reporting of CAHPS for PQRS utilize the Hospital Compare model by displaying aggregate scores for measures with a footnote or click-through option to view the performance data.

Response: We appreciate the commenters' feedback regarding display of CAHPS for PQRS measures. We generally make decisions about measure display after consumer testing and stakeholder outreach, so we will take these recommendations into consideration.

We previously finalized in the 2014 PFS final rule with comment period (78 FR 74454) that 20 measures in the 2014 PQRS measures for individual EPs collected via registry, EHR, or claims would be available for public reporting in late 2015, if technically feasible. We proposed (79 FR 40390) to expand on this in two ways. First, we proposed to publicly report these same 20 measures for 2013 PQRS data in early 2015. We stated that publicly reporting these 2013 individual measures would help ensure individual level measures are made available as soon as possible. We believe that consumers are looking for measures about individual doctors and other health care professionals, and this would make these quality data available to the public sooner.

Comment: One commenter supported our proposal to publicly report 20 individual EP-level 2013 PQRS measures in early 2015, while another commenter opposed the proposal noting that physicians were unaware at the time of data collection that these performance rates would be published. Concerns were raised that timelines needed to be finalized before the public reporting period had ended.

Response: We appreciate the commenters' feedback and understand concerns that the 2013 individual EP PQRS data were submitted without an explicit understanding that these data would be made public. As a result, we are not finalizing this proposal.

Second, we proposed (79 FR 40390) to make all individual EP-level PQRS measures collected via registry, EHR, or claims available for public reporting on Physician Compare for data collected in 2015 to be publicly reported in late CY 2016, if technically feasible.[9] We stated that this would provide the opportunity for more EPs to have measures included on Physician Compare, and it would provide more information to consumers to make informed decisions about their health care. As with group-level measures, we proposed to publicly report all measures submitted and reviewed and deemed valid and reliable in the Physician Compare downloadable file. However, not all of these measures necessarily would be included on the Physician Compare profile pages. Our analysis of the reported measure data, along with consumer testing and stakeholder feedback, would determine specifically which measures are published on profile pages on the website. In this way, quality information on individual practitioners would be available, as has been regularly requested by Medicare consumers, without overwhelming consumers with too much information.

Comment: Some commenters supported expanding public reporting of individual-level quality measures to all 2015 PQRS measures collected through a Registry, EHR, or claims, noting consumers are looking for individual doctors so this information is helpful. Several commenters opposed making 2015 PQRS individual EP measures available for public reporting in 2016 and are concerned that individual quality measurement is technically challenging to validate and may be difficult for consumers to understand. Another commenter suggested it is

[9] Tables Q1-Q27 detail proposed changes to available PQRS measures. Additional information on PQRS measures can be found on the CMS.gov PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

too much information for consumers. One commenter stated that data reported through different reporting mechanisms is not comparable so this proposal should not be finalized. One commenter believed that the relatively small numbers of patients seen by individual physicians raises questions about the ability to truly differentiate quality. Several commenters supported group practice level public reporting as an alternative to individual public reporting.

Response: We appreciate the commenters' feedback and agree with those comments that support individual-level measure data should be posted on the site as soon as technically feasible. We also strongly agree with commenters that these data will help health care consumers make informed decisions about the care they receive. However, we appreciate the concerns raised by other commenters' in opposition to posting individual EP measures. We are committed to including only the most accurate, statistically reliable, and valid quality of care measure data on Physician Compare. We will also ensure that only those data that are evaluated to be comparable will be publicly reported understanding the concerns regarding data collected via different reporting mechanisms.

We will continue to test the PQRS measures with consumers to ensure the measures are presented and described in a way that is accurately understood. We will only include on the website those measures that resonate with consumers to ensure they are not overwhelmed with too much information. Regarding concerns around the number of patients seen, only those measures that are reported for the accepted sample size of 20 patients will be publicly reported. Because of the overwhelming consumer demand for individual EP data and the value these data provide to patients, we are finalizing our proposal to publicly report all 2015 individual EP PQRS measures collected through a Registry, EHR, or claims, except for those measure that are new to PQRS and thus in their first year.

As noted above for group-level reporting, composite scores and benchmarks are critical in helping consumers best understand the quality measure information presented. For that reason, in addition to making all 2015 PQRS measures available for public reporting, we sought comment (79 FR 40390) to create composites and publish composite scores by grouping measures based on the PQRS measure groups, if technically feasible. We indicated that we would analyze the data collected in 2015 and conduct psychometric and statistical analyses to create composites for PQRS measure groups to be published in 2016, including:

- Coronary Artery Disease (CAD) (see Table 30)
- Diabetes Mellitus (DM) (see Table 32)
- General Surgery (see Table 33)
- Oncology (see Table 38)
- Preventive Care (see Table 41)
- Rheumatoid Arthritis (RA) (see Table 42)
- Total Knee Replacement (TKR) (see Table 45)

We would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015. As noted for group practices, we believe that providing composite scores will give consumers the tools needed to most accurately interpret the quality data published on Physician Compare. We would analyze the component measures that make up each of these measure groups to see if a statistically viable composite can be constructed with the data reported for 2015.

As noted above, we received multiple comments about creating composites at both the group practice and individual EP-level. Those comments are addressed above. Since we were only seeking comments on possible future composites, we are not finalizing any at this time, but we will take those comments into consideration for the future.

In addition, we proposed (79 FR 40390) to use the same methodology outlined above for group practices to develop benchmarks for individual practitioners. We believe that providing benchmarks will give consumers the tools needed to most accurately interpret the quality data published on Physician Compare. As discussed above, we received comments on the proposed benchmarking methodology for both group practices and individual EPs. Those comments were previously addressed. As noted, we are not finalizing this proposed benchmarking methodology at this time.

Previously, we indicated an interest in including specialty society measures on Physician Compare. In the proposed rule, we solicited comment (79 FR 40390) on posting these measures on the website. We also solicited comment on the option of linking from Physician Compare to specialty society websites that publish non-PQRS measures. Including specialty society measures on the site or linking to specific specialty society measures would provide the opportunity for more eligible professionals to have measures included on Physician Compare and thus help Medicare consumers make more informed choices. The quality measures developed by specialty societies 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. These measures would provide access to available specialty specific quality measures that are often highly regarded and trusted by the stakeholder community and, most importantly, by the specialties they represent. We indicated that we were working to identify possible societies to reach out to, and solicited comment on the concept, as well as potential specific society measures of interest.

Comment: Many commenters supported specialty society measures on Physician Compare or linking to specialty society websites that publish non-PQRS measures. Several commenters specified that the specialty society measures should be supported by scientific

evidence, developed by relevant clinical experts, and adequately vetted. Some commenters suggested a disclaimer specifying, along with the measure description, the limitations of PQRS or clarification that CMS is not endorsing and has not validated specialty society measures. One commenter supported specialty measures as long as data is open sourced, provided at no cost, and made available to all. One commenter suggested also including links to additional patient-friendly educational materials on specialty societies' websites.

Several commenters opposed posting non-PQRS data or linking to non-governmental, privately managed websites. One commenter stated CMS should maintain control over the public disclosure process to reduce potential for variable data. One commenter is concerned that the approach will lead to more confusion for consumers and added burden for physicians, and another commenter cautioned CMS to ensure measures that are meaningful to consumers and comparable to those reported upon under the PQRS. A few commenters sought additional information on this process if this becomes a formal proposal in future years.

Response: We appreciate commenters' feedback on our request for information. We were only seeking comment at this time. We will consider feedback, recommendations made, and concerns raised, and may consider addressing specialty society measures and website links on Physician Compare in future rulemaking.

Finally, we proposed (79 FR 40390) to make available on Physician Compare, 2015 Qualified Clinical Data Registry (QCDR) measure data collected at the individual level or aggregated to a higher level of the QCDR's choosing – such as the group practice level, if technically feasible. QCDRs are able to collect both PQRS measures and non-PQRS measures.[10] We believe that making QCDR data available on Physician Compare further supports the expansion of quality measure data available for EPs and group practices regardless of specialty

[10] http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip

therefore providing more quality data to consumers to help them make informed decisions. Per the proposal, the QCDR would be required to declare during their self-nomination if they plan to post data on their own website and allow Physician Compare to link to it or if they will provide data to CMS for public reporting on Physician Compare. We proposed that measures collected via QCDRs must also meet the established public reporting criteria, including a 20 patient minimum sample size. As with PQRS data, we proposed to publicly report in the Physician Compare downloadable file all measures submitted, reviewed, and deemed valid and reliable. However, not all of these measures necessarily would be included on the Physician Compare profile pages. Our analysis of the reported measure data, along with consumer testing and stakeholder feedback would determine specifically which measures are published on profile pages on the website.

Comment: We received many comments on publicly reporting 2015 QCDR measure data. Some commenters supported publicly reporting QCDR data to provide specialty-specific quality information for patients. One commenter proposed CMS consumer test QCDR measures to ensure valid sampling, consistent methods, and comparable results across specialties.

A number of commenters did not support the proposal, however. Most notably, commenters believed that public reporting first year data for new measures would be problematic. Other commenters opposed publicly reporting QCDR data until accurate benchmarking data can be developed, or professionals have the opportunity to analyze the data and make improvements. Several commenters requested NQF endorsement for all QCDR measures, and one commenter suggested that CMS develop rules and guidelines for measure stewards who develop non-PQRS measures housed in QCDR's. One commenter stated society-sponsored non-PQRS measures need to be subjected to the same reliability, validity, and consumer testing that CMS promises for other information on Physician Compare. Another

commenter noted that QCDR measures are collected for quality improvement purposes and have not been vetted for public reporting.

Response: We appreciate the commenters' feedback on our proposal to include all 2015 QCDR data at the individual level or aggregated to a higher level of the QCDR's choosing. We understand the many concerns raised. We specifically appreciate the concerns that the QCDR non-PQRS measures be held to the same standards as the PQRS measures in terms of reliability, validity, and accuracy, and that these measures be adequately tested and vetted for public reporting. Understanding these concerns, we will review all data prior to public reporting to ensure that the measures included meet the same standards as the PQRS measures being publicly reported. As with the PQRS measures being made available for public reporting, if the QCDR measures do not meet the requirements for public reporting we have set out, the measures will not be publicly reported. Regarding the comment that QCDR data should not be publicly reported until accurate benchmarks are available, we appreciate this concern but are moving forward with the proposal because we believe that even without benchmarks, these data can provide consumers with very valuable and instructive information as is the case, and thus consistent, with the PQRS measures we are finalizing for publication without a benchmark. We do feel it is important to include QCDR data in our public reporting plan, as some commenters agreed, because using QCDR data can ultimately provide an opportunity to have measures available for public reporting for a greater number of health care professionals covering more specialties, providing more and more useful information to health care consumers. We are therefore finalizing our proposal to publicly report QCDR measures with some modifications.

We agree that it may be problematic to publicly report first year measures. Health care professionals should be afforded the opportunity to simply learn from the first year data, and not have this information shared publicly until the measure can be vetted for accuracy. As a result,

we will not publicly report any QCDR measures newly available for reporting for at least one year. This is consistent with the VM policy regarding first year measures and addresses a significant number of the concerns raised, which were specifically in regard to not including first year measures for public reporting. If first year measures are not publicly reported this will provide us the necessary time to review and vet the QCDR measures to ensure that only those truly suitable for public reporting are posted on Physician Compare when they mature.

Comment: A number of commenters considered the proposed timeline for publicly reporting 2015 QCDR measure data too aggressive to ensure that data will be valid and reliable and in a format which consumers can understand; some suggested delaying or implementing a gradual approach. A few commenters were concerned public reporting so soon will damage start up efforts of new registries.

Several commenters supported the proposal only if the QCDR measures are posted on Physician Compare. One commenter believed this will streamline the public reporting process. One commenter noted that QCDRs websites are not intended for public consumption and would require new infrastructure, while another commenter was concerned with a potential conflict of interest by linking to nongovernmental websites. Two commenters support linking to the QCDR websites to view the data to reduce consumer confusion. Another commenter urged consistent and uniform public reporting.

Response: We appreciate the commenters' feedback and do acknowledge the concerns regarding the timeline. To mitigate some of these concerns, we are adopting some refinements to what we proposed, such as not reporting first year measures. We believe that not publicly reporting measures on Physician Compare that are not ready for public reporting will help QCDRs early in their development and not reflect negatively on the new QCDR. We are also finalizing a decision to publish QCDR 2015 data on the Physician Compare website in 2016.

However, as finalized in the PQRS section of this rule, we are not requiring these data to be publicly reported on the QCDR websites in order to address concerns that there is not enough time for QCDRs to establish user-friendly websites for sharing data as well as concerns about data consistency. Publicly reporting the QCDR data on Physician Compare also provides a uniform public reporting approach, eliminates the need for health care professionals to verify their data in multiple locations, and provides one, user-friendly website for consumers trying to locate quality data. After this first year of pubic reporting QCDR data, we will evaluate if maintaining this policy is most desirable.

Comment: A few commenters supported reporting individual or data aggregating to a higher level, but the majority recommend QCDR measure data only be reported on Physician Compare at the group practice level. One commenter suggested requiring the individual level data to be made publicly available, so long as results are valid and reliable. One commenter believed QCDRs should have the option to publicly disclose performance data by physician specialty within a group, in addition to at the individual or group levels.

Response: We appreciate the commenters' feedback. As stated above, only those data that are deemed valid, reliable, and accurate will be publicly reported on Physician Compare. This will be true for all QCDR data as well. Given that we will publish QCDR data on Physician Compare, but not first year measures, this will enable us to review and vet the QCDR measures prior to public reporting in 2016. In this way, we can ensure only the most appropriate available QCDR measures are publicly reported, and that they are reported in a way that will help consumers make informed decisions.

QCDR data will only be publicly reported at the individual-EP level. We appreciate the commenters' concerns and support for group-level data. However, QCDR data is not necessarily aggregated to a level consistent with how PQRS defines a group practice. Therefore, aggregated

data cannot be accommodated on Physician Compare at this time. And, under PQRS, only individual EPs can report via a QCDR. Therefore, only including individual-level QCDR data on Physician Compare is consistent with the PQRS program's implementation of the data. As with all data included on Physician Compare, only data deemed valid, reliable, and accurate will be publicly reported on the website.

Table 49 summarizes the Physician Compare proposals we are finalizing for with regard to 2015 data.

TABLE 49: Summary of Finalized Data for Public Reporting

Data Collection Year	Publication Year	Data Type	Reporting Mechanism	Finalized Proposals Regarding Quality Measures and Data for Public Reporting
2015	2016	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 individual PQRS Cardiovascular Prevention measures in support of Million Hearts.
2015	2016	PQRS GPRO & ACO GPRO	Web Interface, EHR, Registry, and Administrative Claims	All 2015 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 and all measures reported by ACOs with a minimum sample size of 20 patients.
2015	2016	CAHPS for PQRS& CAHPS for ACOs	CMS-Specified Certified CAHPS Vendor	2015 CAHPS for PQRS for groups of 2 or more EPs and CAHPS for ACOs for those who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2015	2016	PQRS	Registry, EHR, or Claims	All 2015 PQRS measures for individual EPs collected through a Registry, EHR, or claims.
2015	2016	QCDR data	QCDR	All individual-EP level 2015 QCDR data.

4. Additional Comments Received Beyond the Scope of this Rulemaking

We received comments regarding the availability of measures at the individual and group-levels for certain types of specialties and for other health care professionals, but that were beyond the scope of this rule. We have summarized and addressed those comments below.

Comment: Several commenters are concerned about the availability of specialty-specific and non-physician measures available for public reporting due to the proposed removal of PQRS

measures and/or limitations of measures reported via claims or the Web Interface. Two commenters noted that some specialty specific measures are not suitable for public reporting, as the data is not meaningful to consumers. Commenters also 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. Several commenters expressed concern with publicly reporting any data until measure limitations can be analyzed or addressed. Two commenters supported the continued work of CMS with professional societies to address measure concerns.

Response: We appreciate the commenters' feedback. We understand that 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. And, it is important to realize that as most searches on Physician Compare are specialty based, if there are not measures for a given specialty, users will not be evaluating some physicians or non-physicians with measures and some without within that specialty. That can also work to mitigate 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.

Comment: We received comments on how quality measures are displayed on Physician Compare. Several commenters opposed star rankings or similar systems and are concerned that disparate quality scores will result in inappropriate distinctions of quality for physicians whose

performance scores are not statistically different. One commenter suggested increased efforts to establish the best method for presenting performance information to consumers and to educate consumers on the meaning of performance differences.

Response: At the time this rule is finalized, Physician Compare does not employ a ranking system – the site does not provide a system that determines that one professional is better than other professionals based on any set of defined criteria. Performance scores are displayed visually using five stars as a pictographic representation of the percent. In this way, each star represents 20 percentage points. The performance rate is also displayed as a percent. Consumer testing has shown that this display is most accurately understood and interpreted by website users. Stakeholders were provided opportunities to view alternate display options and this display was also supported by a majority of those who took part in review sessions prior to the initial publication of measure data. That said, we intend to continue to work with consumers and stakeholders to find the best way to display data that will best serve consumers and most accurately represent the data.

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 site 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. One commenter requested the definition of the Clinical Nurse Specialist change, while another specified changes for Registered Dietitian/Nutrition Professionals. One commenter asked CMS to assure that audiologists are meaningfully represented and can be easily identified by other professionals and patients. One commenter recommended that the enrollment application process also be refined to provide a provider neutral enrollment process.

Response: We appreciate the commenters' feedback, and will take all recommendations

into consideration for the future. The site was named consistent with section 10331 of the Affordable Care Act. Throughout the site we 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 Fee-For-Service claims in their name in the last 12 months, they will be included on Physician Compare. We are always working to ensure the plain language definitions of the various types of professionals included on the site are accurate and up-to-date. We will review the recommendations made around this information and work with relevant stakeholders to update as appropriate.

Comment: Commenters provided suggestions for additional information to publicly report on Physician Compare, including participation in a quality improvement registry for certain services, fellowship status, other voluntary quality improvement initiatives, educational materials about a disease or procedure, 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. One commenter supported inclusion of information about physician compliance with Medicare rules. Another commenter suggested including measures related to cancer care.

Response: We appreciate the commenters' feedback and recommendations for including additional information on the website. We will review all recommendations provided and evaluate the feasibility for potential inclusion in the future. One important consideration around many of these recommendations is whether there is a readily available national-level data source. With this in mind, the recommendations will be closely evaluated.

Comment: Several commenters noted the limitations of CAHPS for PQRS measures for some health care professionals and supported adding other types of patient experience data to Physician Compare, including the Surgical CAHPS® and experience data collected via other

sources. One commenter suggested publicly reporting beneficiary satisfaction information in addition to CAHPS for PQRS measures. Another commenter suggested reporting patient experience data for primary care physicians and clinical quality performance for specialists.

Response: We appreciate the commenters' feedback. We agree that Surgical CAHPS® data is useful to consumers and we are exploring how we can incorporate this information into Physician Compare.

Comment: One commenter encouraged CMS to recognize improvements by individual professionals and groups over time, while another noted the benefits of cross-sectional and cross-time comparisons.

Response: We appreciate the commenters' feedback and the recommendation to consider longitudinal as well as other comparisons. We will evaluate these recommendations as we move forward with Physician Compare.

Comment: One commenter suggested that the measures being removed from PQRS due to 100 percent performance be added to the Physician Compare website as display measures believing that these topped out measures would add value to Physician Compare.

Response: We appreciate the commenter's feedback. However, if the measure data are no longer going to be reported in PQRS, these data will not be available to consider for posting on Physician Compare.

Comment: One commenter urged CMS to create mechanisms to attribute Medicare Advantage quality data to physician groups for display on Physician Compare and enable CG-CAHPS vendors to include beneficiaries enrolled in MA, as well as in traditional Medicare fee-for-service.

Response: We appreciate the commenters' suggestions and will evaluate the feasibility of these recommendations for the future.

5. Report to Congress

Section 10331(f) of the Affordable Care Act, requires that no later than January 1, 2015, we submit a report to Congress on the Physician Compare website that includes information on the efforts of and plans made by the Secretary of Health and Human Services to collect and publish data on physician quality and efficiency and on patient experience of care in support of consumer choice and value-based purchasing. We anticipate timely submission of this report, including discussion about the phase-in of the website and developments to date. The report will also address the expansion of data on the website, in regard to section 10331(g) of the Affordable Care Act, and future plans for the website.

K. 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 (ending with 2014) and payment adjustments (beginning in 2015) to eligible professionals 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 eligible professionals that satisfactorily participate in a qualified clinical data registry (QCDR).

The requirements in this rule primarily focus on the 2017 PQRS payment adjustment, which will be based on an eligible professional's or a group practice's reporting of quality measures data during the 12-month calendar year reporting period occurring in 2015 (that is, January 1 through December 31, 2015). Please note that, during the comment period, we received comments that were not related to our specific proposals for the requirements for the 2017 PQRS payment adjustment in the CY 2015 PFS proposed rule. While we appreciate the commenters' feedback, these comments will not be specifically addressed in this CY 2015 PFS final rule with comment period, as they are beyond the scope of this rule. However, we will consider these comments when developing policies and program requirements for future years. Please note that we continue to focus on aligning our requirements with other quality reporting programs, such as the Medicare EHR Incentive Program for Eligible Professionals, the VM, and the Medicare Shared Savings Program, where and to the extent appropriate and feasible.

The PQRS regulations are located at §414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustment 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 2012 PQRS and eRx Experience Report, which provides information about eligible professional participation in PQRS, is available for download at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2012-PQRS-and-eRx-Experience-Report.zip.

We note that eligible professionals 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 Medicare reimburses eligible professionals in CAH-IIs, it is feasible for eligible professionals in CAH-IIs to participate in the PQRS for reporting beginning in 2014. Although eligible professionals in CAH-IIs are not able to use the claims-based reporting mechanism to report PQRS quality measures data in 2014, beginning in 2015, these eligible professionals in CAH-IIs may participate in the PQRS using ALL reporting mechanisms available, including the claims-based reporting mechanism. Finally, please note that in accordance with section 1848(a)(8) of the Act, all eligible professionals who do not meet the criteria for satisfactory reporting or satisfactory participation for the 2017 PQRS payment adjustment will be subject to the 2017 PQRS payment adjustment with no exceptions.

In addition, in the CY 2013 PFS final rule with comment period, we introduced the reporting of the Agency for Healthcare Research and Quality's (AHRQ's) Clinician & Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures, referenced at https://cahps.ahrq.gov/Surveys-Guidance/CG/index.html. AHRQ's CAHPS Clinician & Group Survey Version 2.0 (CG-CAHPS) includes 34 core CG-CAHPS survey questions. In addition to these 34 core questions, the CAHPS survey measures that are used in the PQRS include supplemental questions from CAHPS Patient-Centered Medical Home Survey, Core CAHPS Health Plan Survey Version 5.0, other CAHPS supplemental items, and some additional questions. Since the CAHPS survey used in the PQRS covers more than just the 34 core CG-CAHPS survey measures, we will refer to the CG-CAHPS survey measures used in the PQRS as "CAHPS for PQRS." We proposed to make this revision throughout §414.90. We did not receive comments on referring to the CG-CAHPS survey measures as reported in the PQRS as CAHPS for PQRS, and are therefore finalizing this proposal as proposed.

1. 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 Group Practice Reporting Option (GPRO) web interface; certified survey vendors, for the 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 III.K.1 contains our proposals to change the qualified registry, direct EHR and EHR data submission vendor products, QCDR, and GPRO web interface reporting mechanisms, as well as public comments and our final decisions on those proposals. Please note that we did not propose to make changes to the claims-based reporting mechanism.

Please note that, in the CY 2015 PFS proposed rule, we solicited comments on whether, in future years, we should allow for more frequent submissions, such as quarterly or year-round submissions, for PQRS quality measures data submitted via the qualified registry, EHR, QCDR, and GPRO web interface reporting mechanisms (79 FR 40392, 40393, and 40395 respectively). Many commenters supported this concept, as it would provide vendors and their products greater flexibility in data submission. However, some of these commenters who expressed support for more frequent submissions of data preferred that the ability to provide more frequent submission of data be optional, not mandatory. We appreciate the commenters' support for this concept and will consider the commenters' feedback if and when we propose this policy in future rulemaking.

a. Changes to the Requirements for the Qualified Registry

In the CY 2013 and 2014 PFS final rules with comment period, we established certain requirements for entities to become qualified registries for the purpose of verifying that a qualified registry is prepared to submit data on PQRS quality measures for the reporting period in which the qualified registry seeks to be qualified (77 FR 69179 through 69180 and 78 FR 74456). Specifically, in the CY 2014 PFS final rule with comment period, in accordance with the satisfactory reporting criterion we finalized for individual eligible professionals or group practices reporting PQRS quality measures via qualified registry, we finalized the following requirement that a qualified registry must be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the National Quality Strategy (NQS) domains (78 FR 74456).

As we explain in further detail in this section III.K, we proposed that – in addition to requiring that an eligible professional or group practice report on at least 9 measures covering 3 NQS domains –an eligible professional or group practice who sees at least 1 Medicare patient in a face-to-face encounter, as

we define that term in section III.K.2.a., and wishes to meet the criterion for satisfactory reporting of PQRS quality measures via a qualified registry for the 2017 PQRS payment adjustment would be required to report on at least 2 cross-cutting PQRS measures specified in Table 52. In accordance with this proposal, we proposed to require that, in addition to being required to be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the NQS domains for which a qualified registry transmits data, a qualified registry would be required to be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for ALL cross-cutting measures specified in Table 52 for which the registry's participating eligible professionals are able to report.

Comment: Some commenters opposed this proposed requirement, stating that this requirement seems overly burdensome. The commenters noted that, in some instances, certain registries report PQRS quality measures data for certain specialties for which the proposed cross-cutting measure set does not apply. Commenters also requested exceptions to this requirement for "closed registries," which the commenter defined as registries not open to all eligible professionals for participation.

Response: We understand the commenters' concerns regarding requiring registries to be able to report on all cross-cutting measures specified in Table 52. We made this proposal to allow eligible professionals and group practices the option to report on as many cross-cutting measures as are applicable. However, we understand that it may by overly burdensome for certain registries, such as those registries geared towards specialties for which the cross-cutting measures do not apply or "closed registries." Therefore, based on the comments received, we are not finalizing our proposal to require that qualified registries be able to report on all cross-cutting measures specified in Table 52 for which the registry's participating eligible professionals are able to report. We note, however, as we describe in greater detail below, eligible professionals and group practices using the registry-based reporting mechanism that see at least 1 Medicare patient in a face-to-face encounter must still report on 1 cross-cutting measure to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Therefore, in order for the registry's participating eligible professionals and group practices to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, the registry must be able to

report to report on at least 1 cross-cutting measure on behalf of its participating eligible professionals and group practices.

Furthermore, in the CY 2013 PFS final rule, we noted that qualified registries have until the last Friday of February following the applicable reporting period (for example, February 28, 2014, for reporting periods ending in 2013) to submit quality measures data on behalf of its eligible professionals (77 FR 69182). We continue to receive stakeholder feedback, particularly from qualified registries currently participating in the PQRS, urging us to extend this submission deadline due to the time it takes for these qualified registries to collect and analyze the quality measures data received after the end of the reporting period. Although, at the time, we emphasized the need to have quality measures data received by CMS no later than the last Friday of the February occurring after the end of the applicable reporting period, we believe it is now feasible to extend this deadline. Therefore, we proposed to extend the deadline for qualified registries to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015). We invited and received the following public comments on this proposal:

Comment: Commenters supported this proposal, as it would allow qualified registries an additional month to submit quality measures data.

Response: We appreciate the commenters' positive feedback. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal to extend the deadline for qualified registries to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015).

b. Changes to the Requirements for the Direct EHR and EHR Data Submission Vendor Products That Are CEHRT

In the CY 2013 PFS final rule with comment period, we finalized requirements that although EHR vendors and their products would no longer be required to undergo the previously existing qualification process, we would only accept the data if the data are: (1) transmitted in a CMS-approved

XML format utilizing a Clinical Document Architecture (CDA) standard such as Quality Reporting Data Architecture (QRDA) level 1 (and for EHR data submission vendor products that intend to report for purposes of the proposed PQRS-Medicare EHR Incentive Program Pilot, if the aggregate data are transmitted in a CMS-approved XML format); and (2) in compliance with a CMS-specified secure method for data submission (77 FR 69183 through 69187). To further clarify, EHR vendors and their products must be able to submit data in the form and manner specified by CMS. Accordingly, direct EHRs and EHR data submission vendors must comply with CMS Implementation Guides for both the QRDA-I and QRDA-III data file formats. The Implementation Guides for 2014 are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Guide_QRDA_2014eCQM.pdf. Updated guides for 2015, when available, will be posted on the CMS EHR Incentive Program website at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms. These implementation guides further describe the technical requirements for data submission to ensure the data elements required for measure calculation and verification are provided. We proposed to continue applying these requirements to direct EHR products and EHR data submission vendor products for 2015 and beyond. We received no public comment on our proposal to continue applying these requirements. Therefore, we are finalizing our proposal to have direct EHRs and EHR data submission vendors comply with CMS Implementation Guides for both the QRDA-I and QRDA-III data file formats for 2015 and beyond.

For 2015 and beyond, we also proposed to have the eligible professional or group practice provide the CMS EHR Certification Number of the product used by the eligible professional or group practice for direct EHRs and EHR data submission vendors. We believe this requirement is necessary to ensure that the eligible professionals and group practices that are using EHR technology are using a product that is certified EHR technology (CEHRT) and will allow CMS to ensure that the eligible professional or group practice's data is derived from a product that is CEHRT. We solicited but received no public comment on this proposal. However, we do not believe it is feasible for us to collect this

information at this time, because we do not have a venue in which to store this information. Therefore, we are not finalizing this proposal.

c. Changes to the Requirements for the QCDR

Reporting Outcome Measures:

In accordance with the criterion for satisfactory participation in a QCDR that we proposed for the 2017 PQRS payment adjustment, we proposed to require a QCDR to possess at least 3 outcome measures (or, in lieu of 3 outcome measures, at least 2 outcome measures and at least 1 of the following other types of measures - resource use, patient experience of care, or efficiency/appropriate use) (79 FR 40393). We solicited and received the following comment on this proposal:

Comment: The majority of commenters opposed this proposal. The commenters believed this proposed requirement was overly burdensome, particularly for the QCDRs that do not have 3 outcome measures available for reporting currently. The commenters urged CMS not to bring about change to a reporting option that is still relatively new.

Response: We understand the commenters' concerns. As we describe in greater detail in section III.K.3.a. below, we are modifying our final criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment by only requiring that an eligible professional report on at least 2 outcome measures (or, in lieu of 2 outcome measures, at least 1 outcome measure and 1 of the following other types of measures – resource use, patient experience of care, efficiency/appropriate use, or safety). Since this proposal was intended to be consistent with our final criterion for the satisfactory participation in a QCDR for the 2017 PQRS payment adjustment, we are modifying this proposal and finalizing the following requirement for QCDRs: a QCDR must possess at least 2 outcome measures. If the QCDR does not possess 2 outcome measures, then, in lieu of 2 outcome measures, the QCDR must possess at least 1 outcome measures and 1 of the following other types of measures – resource use, patient experience of care, efficiency/appropriate use, or safety. We believe this modification does not significantly change the current QCDR requirement to possess at least 1 outcome measure, as a QCDR may still possess only one measure for reporting in 2015 and still qualify to become or remain a QCDR

provided that the QCDR possesses 1 of the following other types of measures – resource use, patient experience of care, efficiency/appropriate use, or safety.

Reporting Non-PQRS Measures:

To establish the minimum number of measures (9 measures covering at least 3 NQS domains) a QCDR may report for the PQRS, we placed a limit on the number of non-PQRS measures (20) that a QCDR may submit on behalf of an eligible professional at this time (78 FR 74476). We proposed to change this limit from 20 measures to 30 (79 FR 40393). We solicited and received the following public comment on this proposal:

Comment: Some commenters supported this proposal, as it would allow QCDRs to report on more measures that may cover a broader range of specialties and sub-specialties. A few commenters opposed this proposal, as the commenters urged CMS not to bring about change to a reporting option that is still relatively new.

Response: We appreciate the commenters' positive feedback. While we understand the need to provide continuity and stability in this reporting option, particularly during its early stages, we believe that the benefits of allowing QCDRs potentially to cover a broader range of specialties and sub-specialties outweigh the commenters' concerns. Therefore, we are finalizing our proposal that beginning with the criteria for satisfactory participation for the 2017 PQRS payment adjustment, a QCDR may submit quality measures data for a maximum of 30 non-PQRS measures. Please note that this limit does not apply to measures contained in the PQRS measure set, as QCDRs can report on as many measures in the PQRS measure set as they wish. Also, please note that QCDRs are not required to report on 30 non-PQRS measures. Rather, the reporting of non-PQRS measures is optional, and our final rule here increases the number of optional additional measures that a QCDR may elect to submit.

Definition of a Non-PQRS Measure:

Additionally, CMS' experience during the 2014 self-nomination process shed light on clarifications needed on what is considered a non-PQRS measure. Therefore, to clarify the definition of non-PQRS measures, we proposed the following parameters for a measure to be considered a non-PQRS measure:

- A measure that is not contained in the PQRS measure set for the applicable reporting period.
- A measure that may be in the PQRS measure set but has substantive differences in the manner it is reported by the QCDR. For example, PQRS measure 319 is reportable only via the GPRO web interface. A QCDR wishes to report this measure on behalf of its eligible professionals. However, as CMS has only extracted the data collected from this quality measure using the GPRO web interface, in which CMS utilizes a claims-based assignment and sampling methodology to inform the groups on which patients they are to report, the reporting of this measure would require changes to the way that the measure is calculated and reported to CMS via a QCDR instead of through the GPRO web interface. Therefore, due to the substantive changes needed to report this measure via a QCDR, PQRS measure 319 would be considered a non-PQRS measure. In addition, CAHPS for PQRS is currently reportable only via a CMS-certified survey vendor. However, although CAHPS for PQRS is technically contained in the PQRS measure set, we consider the changes that will need to be made to be available for reporting by individual eligible professionals (and not as a part of a group practice) significant enough as to treat CAHPS for PQRS as a non-PQRS measure for purposes of reporting CAHPS for PQRS via a QCDR.

To the extent that further clarification on the distinction between a PQRS and a non-PQRS measure is necessary, we will provide additional guidance on our website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html.

Public Reporting of QCDR Quality Measures Data:

Furthermore, under our authority to establish the requirements for an entity to be considered a QCDR under section 1848(m)(3)(E)(i) of the Act, we established certain requirements for an entity to be considered a QCDR in the CY 2014 PFS final rule with comment period (78 FR 74467 through 74473). Under this same authority, we proposed here to add the following requirement that an entity must meet to serve as a QCDR under the PQRS for reporting periods beginning in 2015:

- Require that the entity make available to the public the quality measures data for which its eligible professionals report.

To clarify this proposal, we proposed that, at a minimum, the QCDR publicly report the following quality measures data information that we believe will give patients adequate information on the care

provided by an eligible professional: the title and description of the measures that a QCDR reports for purposes of the PQRS, as well as the performance results for each measure the QCDR reports. We solicited and received the following public comment on this proposal:

Comment: Some commenters supported this proposal, as the commenters believed it was reasonable to require that this information be made available to the public. These commenters supported our proposal to defer to the QCDR in terms of what platform and in what manner this data may be made available to the public. Some commenters opposed this proposal, stating that the public reporting requirement was overly burdensome, and urged CMS to delay requiring the posting of measures data until the measures have been tested for validity and reliability. The commenters believed that CMS should not make substantial changes in the QCDR requirements as the QCDR option is new and the entities need time to familiarize themselves with the QCDR option before new requirements are established.

Response: With respect to the commenters who opposed this proposal and urged CMS not to make additional changes to the QCDR option while entities become more familiar with this option, we understand the commenters' concerns. However, we believe that transparency of data is a key component of a QCDR option. We believe that it is appropriate to finalize this public reporting requirement at this time. In the CY 2014 PFS final rule, while we did not finalize our proposal that a QCDR have a plan to publicly report quality measures data, we noted that we encouraged "these qualified clinical data registries to move towards the public reporting of quality measures data" and that we planned to "establish such a requirement in the future" and would "revisit this proposed requirement as part of CY 2015 rulemaking" (78 FR 74471). Therefore, we believe that QCDRs were on notice that we would propose and finalize a requirement to make quality measures data available to the public beginning with the CY 2015 reporting.

However, although we do not believe we should further delay requiring public report of QCDR quality measures data, we do agree with the commenters on delaying public posting of measures information until a measure has been tested for validity and reliability. Therefore, we are providing an exception to this requirement for new measures (both PQRS and non-PQRS measures) that are in their first year of reporting by a QCDR under the PQRS. We define a measure being introduced in the PQRS

for the first time as the first time a quality measure is either introduced in the PQRS measure set in rulemaking as a new measure for that reporting period or, for non-PQRS measures that can be reported by a QCDR, the first time a QCDR submits a measure (including its measure specifications) for reporting for the PQRS for the first time. Please note that, to the extent that a QCDR first reports on a non-PQRS measure that is already being reported by another QCDR, we would consider the measure a measure that is in its first year of reporting for that respective QCDR who is reporting the measure for the first time. We believe that providing QCDRs with one year to test and validate new measures provides sufficient time for QCDRs to find potential data issues and correct those issues prior to a measure's second year of reporting in the PQRS.

Based on the comments received and for the reasons stated in the proposed rule, we are finalizing this proposal to require that the entity make available to the public the quality measures data for which its eligible professionals report. However, as we explained above, we are providing an exception to this requirement for new PQRS and non-PQRS measures that are in their first year of reporting by a QCDR under the PQRS. Therefore, quality measure data for a PQRS or non-PQRS measure that is being reported by a QCDR in the PQRS for the first time does not need to be posted for at least the initial year. After the initial year of reporting a new measure, as we believe it is important for a QCDR to be transparent in the quality performance of its eligible professionals, quality measures performance data for the measure (except for the data collected in the measure's first year of reporting in the PQRS) would be required to be made available to the public.

Please note that, in finalizing these requirements on public reporting, we defer to the entity in terms of the method it will use to publicly report the quality measures data it collects for the PQRS. For example, to meet this requirement, it would be sufficient for a QCDR to publicly report performance rates of eligible professionals through means such as board or specialty websites, or listserv dashboards or announcements. We also note that a QCDR would meet this public reporting requirement if the QCDR's measures data were posted on Physician Compare. In addition, we defer to the QCDR to determine whether to report performance results at the individual eligible professional level or aggregate the results for certain sets of eligible professionals who are in the same practice together (but who are not registered

as a group practice for the purposes of PQRS reporting). We believe it is appropriate to allow a QCDR to publicly report performance results at an aggregate level for certain eligible professionals when those who are in the same practice contribute to the overall care provided to a patient.

- With respect to when the quality measures data must be publicly reported, we proposed that the QCDR must have the quality measures data by April 31 of the year following the applicable reporting period (that is, April 31, 2016, for reporting periods occurring in 2015). The deadline of April 31 will provide QCDRs with one month to post quality measures data and information following the March 31 deadline for the QCDRs to transmit quality measures data for purposes of the PQRS payment adjustments. Please note that we erroneously stated the proposed deadline as April 31, which does not exist in the calendar. We intended to propose a deadline that falls at the end of April—specifically, a deadline of April 30, not April 31, of the year following the applicable reporting period (that is, April 30, 2016, for reporting periods occurring in 2015). This was an inadvertent technical error, and we are therefore correcting this proposal here and our responses to comments below to reflect our intention to propose a deadline of April 30 of the year following the applicable reporting period. We believe this does not materially modify this proposal, and as April 31 does not exist in the calendar, we believe that the public and commenters could reasonably infer that we intended to refer to the end of April in this proposed deadline, which is April 30 and thus reasonably foresee that we would adopt such a deadline. Therefore, we will address the comments and frame our responses below as they relate to an April 30 deadline of the year following the applicable reporting period (that is, April 30, 2016, for reporting periods occurring in 2015). We also proposed that this data be available on a continuous basis and be continuously updated as the measures undergo changes in measure title and description, as well as when new performance results are calculated. We solicited and received the following public comments on this proposal:

Comment: A few commenters opposed our proposal to require that a QCDR must have the quality measures data by April 30 of the year following the applicable reporting period. The commenter noted that any performance data publicly posted should be tested for accuracy and reliability. One commenter stated that QCDRs need more time following the QCDR submission deadline of March 31 to

publicly post quality measures data. Another commenter noted that this timeline is more aggressive than that proposed on Physician Compare.

Response: We believe that the proposed April 30 deadline to make available quality measures data (except for PQRS and non-PQRS measures in their initial year of reporting under the PQRS) is reasonable, as we assume QCDRs would have already tested quality measures data and results for accuracy and reliability for the particular reporting period prior to submitting these quality measures data calculations and results by the March 31 submission deadline. However, we agree with the commenter on the need to provide accurate and reliable data prior to the data being publicly reported. Therefore, given concerns from commenters that April 30 does not provide the QCDRs with enough time to accurately post quality measures data, we are extending the deadline by which a QCDR must publicly report quality measures data outside of Physician Compare to the deadline by which Physician Compare posts QCDR quality measures data as discussed in section III.J above. That is, as indicated in Table 49 in section III.J.3 above, QCDRs wishing to publicly report quality measures data outside of Physician Compare must do so in 2016.

Proposals Related to Collaboration of Entities to Become a QCDR:

Based on our experience with the qualifying entities wishing to become QCDRs for reporting periods occurring in 2014, we received feedback from many organizations who expressed concern that the entity wishing to become a QCDR may not meet the requirements of a QCDR solely on its own. Therefore, we provided the following proposals beginning in 2015 on situations where an entity may not meet the requirements of a QCDR solely on its own but, in conjunction with another entity, may be able to meet the requirements of a QCDR and therefore be eligible for qualification:

- We proposed to allow that an entity that uses an external organization for purposes of data collection, calculation or transmission may meet the definition of a QCDR so long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organizations effective as of January 1 the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2014, to be eligible to participate for purposes of data collected in 2015). Entities that have a mere verbal, non-written agreement to work together to become a QCDR by

January 1 the year prior to the year for which the entity seeks to become a QCDR would not fulfill this proposed requirement. We solicited and received the following public comment on this proposal:

Comment: A few commenters supported this proposal, as it allowed entities such as medical boards that may not have the technical capabilities to submit quality measures data calculations and results to CMS to collaborate with other entities.

Response: We appreciate the commenters' support. Based on the comments received, for the reasons stated here, and in the proposed rule, we are finalizing this proposal.

- In addition, we proposed that an entity that has broken off from a larger organization may be considered to be in existence for the purposes of QCDR qualification as of the earliest date the larger organization begins continual existence. We received questions from entities who used to be part of a larger organization but have recently become independent from the larger organization as to whether the entities would meet the requirement established in the CY 2014 PFS final rule with comment period that the entity be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR (78 FR 74467). For example, a registry that was previously a part of a larger medical society as of January 1, 2013, could have broken off from the medical society and become an independent registry in 2014. Likewise, a member of a medical society could create a registry separate from the medical society. As such, there would be concern as to whether that entity would meet the requirement of being in existence prior to January 1, 2013, to be considered for qualification for reporting periods occurring in 2014. In these examples, for purposes of meeting the requirement that the entity be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR, we may consider this entity as being in existence as of the date the larger medical society was in existence. We solicited and received the following comments on this proposal:

Comment: Commenters supported this proposal.

Response: We appreciate the commenters' support and, based on the comments received and for the reasons stated above, we are finalizing this proposal.

Data Submission Deadline:

In the CY 2014 PFS final rule with comment period, in accordance with the submission deadline of quality measures data for qualified registries, we noted a deadline of the last Friday in February occurring after the end of the applicable reporting period to submit quality measures data to CMS (78 FR 74471). In accordance with our proposal to extend this deadline for qualified registries, we proposed to extend the deadline for QCDRs to submit quality measures data calculations and results by March 31 following the end of the applicable reporting period (that is, March 31, 2016, for reporting periods ending in 2015).

We solicited and received the following public comments on this proposal:

Comment: Commenters supported this proposal, as it would allow qualified registries an additional month to submit quality measures data and aligns with our proposal to extend the submission deadline for qualified registries.

Response: We appreciate the commenters' positive feedback. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal to extend the deadline for QCDRs to submit quality measures data, including, but not limited to, calculations and results, to March 31 following the end of the applicable reporting period (for example, March 31, 2016, for reporting periods ending in 2015).

d. Changes to the GPRO Web Interface

In the CY 2014 PFS final rule with comment period (78 FR 74456), we finalized our proposal to require "that group practices register to participate in the GPRO by September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014), as proposed." However, we noted that, in order "to respond to the commenters concerns to provide timelier feedback on performance on CG CAHPS in the future, we anticipate proposing an earlier deadline for group practices to register to participate in the GPRO in future years" (78 FR 74456). Indeed, to provide timelier feedback on performance on CAHPS for PQRS, we proposed to modify the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015). Specifically, although we still seek to provide group practices with as much time as feasible to decide whether to register to participate

in the PQRS as a GPRO, we weigh this priority with others, such as our desire to provide more timely feedback to participants of the PQRS, as well as other CMS quality reporting programs such as the VM. Therefore, in an effort to provide timelier feedback, we proposed to change the deadline by which a group practice must register to participate in the GPRO to June 30 of the applicable 12-month reporting period (that is, June 30, 2015, for reporting periods occurring in 2015). This proposed change would allow us to provide timelier feedback while still providing group practices with over 6 months to determine whether they should participate in the PQRS GPRO or, in the alternative, participate in the PQRS as individual eligible professionals. Although this proposed GPRO registration deadline would provide less time for a group practice to decide whether to participate in the GPRO, we believe the benefit of providing timelier feedback reports outweighs this concern. We solicited and received the following public comments on these proposals:

Comment: Some commenters supported our proposal to shorten the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015) in order to provide timelier feedback reports. Other commenters opposed our proposal to shorten the deadline from September 30 to June 30, as the commenters believed that the extra time was needed to weigh the advantages and disadvantages of all the reporting options prior to registering for the GPRO and electing a reporting mechanism. One commenter noted that this is particularly important when reporting via EHR, as updates are required for EHR products. Some commenters requested that information for the various reporting mechanisms, such as the list of qualified registries for the reporting period, be made available earlier. Other commenters believed that it would be difficult for group practices to transition to an earlier registration date and requested that CMS delay finalizing this proposal to 2016. Other commenters stated that the proposed deadline would negatively affect group practices that change their Taxpayer Identification Number (TIN) after June 30, as the group practice would be required to report individually, adding to administrative and reporting burden.

Response: With respect to the comments opposing this proposal, we believe that June 30 provides group practices with ample time to decide to register to participate in the PQRS as a GPRO, as

well as choose a reporting mechanism. With respect to the concern of having to choose a reporting option and not having all information on the PQRS reporting options prior to the June 30 deadline, we note that CMS makes numerous guidance documents available on the CMS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html, and group practices can submit any questions to the QualityNet Help Desk at Qnetsupport@hcqis.org. With respect to some commenters' requests that information for the various reporting mechanisms, such as the list of qualified registries for the reporting period, be made available earlier, we note that the list of qualified registries for 2014 – available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014QualifiedRegistries.pdf -- was made available in May 2014, prior to June 30, 2014, and we anticipate making the list of qualified registries for the given reporting period available in advance of the proposed June 30 registration deadline. With respect to the commenters who stated that the proposed deadline would negatively affect group practices that change their Taxpayer Identification Numbers (TINs) after June 30, as the group practice would be required to report individually, adding to administrative and reporting burden, we understand this potential burden. We note that this proposed deadline is only 3 months earlier than the September 30 registration deadline we finalized in the CY 2014 PFS final rule (78 FR 74455). Therefore, we believe the issues associated with group practices that change their TINs would be exacerbated by finalizing the proposed June 30th registration deadline or ameliorated by keeping the current September 30 registration deadline. To the extent that finalizing an earlier deadline would increase the number of group practices affected by these issues, we believe that our interest in providing feedback sooner outweighs the concern of those group practices that change their TINs after June 30 not being able to participate in the GPRO. Based on the reasons stated here and in the proposed rule, we are finalizing our proposal to modify the deadline that a group practice must register to participate in the GPRO to June 30 of the year in which the reporting period occurs (that is, June 30, 2015, for reporting periods occurring in 2015). Please note that this GPRO registration deadline refers to all group practices wishing to participate in the GPRO using any reporting mechanism available for reporting in the GPRO (that is, GPRO web interface, registry, EHR, and/or CMS-certified survey vendor).

2. Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2017 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 eligible professional during 2015 or any subsequent year, if the eligible professional 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 Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2014 PFS final rule with comment period (see Table 47 at 78 FR 74479), we finalized the following criteria for satisfactory reporting for the submission of individual quality measures via claims and registry for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, the eligible professional would report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the eligible professional, report 1—8 measures, 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 eligible professional who reports fewer than 9 measures covering less than 3 NQS domains via the claims- or registry-based reporting mechanism, the eligible professional would be subject to the measure application validity (MAV) process, which would allow us to determine whether the eligible professional should have reported quality data codes for additional measures.

To be consistent with the satisfactory reporting criterion we finalized for the 2014 PQRS incentive, for the 2017 PQRS payment adjustment, we proposed to modify §414.90(j) and proposed the following criterion for individual eligible professionals reporting via claims and registry: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional 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 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, as we proposed to define that term below, the eligible professional would report on at least 2 measures contained in the proposed cross-cutting measure set specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), 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 (79 FR 40395).

We noted that, unlike the criterion we finalized for the 2014 PQRS incentive, we proposed to require an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter, as we defined that term below, during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the cross-cutting measure set specified in Table 52. As we noted in the CY 2014 PFS proposed rule (78 FR 43359), we are dedicated to collecting data that provides us with a better picture of the overall quality of care furnished by eligible professionals, particularly for the purpose of having PQRS reporting being used to assess quality performance under the VM. We believe that requiring an eligible professional to report on at least 2 broadly applicable, cross-cutting measures will provide us with quality data on more varied aspects of an eligible professional's practice. We also noted that in its 2014 pre-rulemaking final report (available at http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx), the Measure Applications Partnership (MAP) encouraged the development of a core measure set (see page 16 of the "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs"). The MAP stated, "a core [measure set] would address critical improvement gaps, align payment incentives across clinician types, and reduce reporting burden."

For what defines a "face-to-face" encounter, for purposes of reporting of at least 2 cross-cutting measures specified in Table 52, we proposed to determine whether an eligible professional had a "face-to-

face" encounter by seeing whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional 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 required reporting of at least 2 cross-cutting measures specified in Table 52 (79 FR 40395 and40396).

In addition, we understand that there may be instances where an eligible professional may not have at least 9 measures applicable to an eligible professional's practice. In this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 47 at 78 FR 74479), an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1-8 measures, as applicable, to the eligible professional's practice. If an eligible professional reports on 1-8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we proposed (79 FR 40396) to implement for claims and registry is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive.

We solicited public comment on our satisfactory reporting criterion for individual eligible professionals reporting via claims or registry for the 2017 PQRS payment adjustment. The following is a summary of the comments we received regarding our proposal for satisfactory reporting criterion for individual eligible professionals reporting via claims or registry for the 2017 PQRS payment adjustment.

Comment: A few commenters supported our intention to move towards eliminating the claims-based reporting option, while the majority of the commenters opposed our proposals related to moving away from the claims-based reporting option. Some of these commenters noted that, for certain eligible professionals, the claims-based reporting mechanism remains the only option by which eligible professionals may report PQRS quality measures data, as many eligible professionals do not have the capabilities to report via EHR or registry. The commenters believe the claim-based reporting mechanism

is a necessary option for eligible professionals with limited resources, such as solo practitioners. Should we intend to phase out this reporting mechanism, commenters urged a gradual phase out of the claims-based reporting mechanism.

Response: We appreciate the commenters' feedback. We understand the concerns associated with moving away from the claims-based reporting mechanism. For the 2017 PQRS payment adjustment, we are finalizing an option by which eligible professionals may meet the criteria for satisfactory reporting by using the claims-based reporting mechanism. Eligible professionals using the other reporting mechanisms have seen greater success at meeting the criteria for satisfactory reporting for the PQRS. However, while we continue to eliminate measures available for reporting via claims, we understand the importance of maintaining the claims-based reporting mechanism as an option at this time. We understand that the claims-based reporting mechanism remains the most popular reporting mechanism. However, to streamline the PQRS reporting options, as well as to encourage reporting options where eligible professionals are found to be more successful in reporting, it is our intention to eliminate the claims-based reporting mechanism in future rulemaking. During this time, we encourage eligible professionals to use alternative reporting methods to become familiar with reporting mechanisms other than the claims-based reporting mechanism.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Some of these commenters noted that eligible professionals have been successful at meeting the criteria for satisfactory reporting for the PQRS incentives and payment adjustments in the past by reporting 3 measures, and increasing the number of measures to be reported would make it more difficult for these eligible professionals to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Other commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a

lower reporting threshold for those eligible professionals practicing in specialties for which few PQRS measures exist.

Response: While we understand the commenters concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare for reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for the satisfactory reporting for the 2016 PQRS payment adjustment via claims and registry that only required the reporting of 3 measures covering 1 NQS domain (see Table 48 at 78 FR 74480). However, we also finalized criteria for the 2016 PQRS payment adjustment using the claims- and registry-based reporting mechanisms that aligned with the following criteria we finalized for the 2014 PQRS incentive: Report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1-9 measures covering 1-3 NQS domains, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measures applies (see Table 48 at 78 FR 74480). Additionally, in the CY 2014 PFS final rule, we noted that "it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive" (78 FR 74465). We believe that establishing criteria for the satisfactory reporting of the 2016 PQRS payment adjustment that are consistent with these proposed criteria, as well as signaling our intent to ramp up the satisfactory reporting criteria, provided enough advance notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, with respect to those commenters concerned that an eligible professional may not have 9 measures covering at least 3 NQS domains applicable to his/her practice, in the proposed rule we noted that in this instance, like the criterion we finalized for the 2014 PQRS incentive (see Table 47 at 78 FR 74479), an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1–8 measures, as applicable, to the eligible professional's practice. If an eligible professional reports on 1–8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine

whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. As such, under this proposed criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional who does not have at least 9 measures covering at least 3 NQS domains applicable to his/her practice may still meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment provided that the eligible professional reports all measures as are applicable to his/her practice.

Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require the reporting of 9 measures covering at least 3 NQS domains to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

In the case that an eligible professional may not have at least 9 measures applicable to an eligible professional's practice, the eligible professional may still be able to meet the satisfactory reporting criterion via claims and/or registry for the 2017 PQRS payment adjustment if the eligible professional reports on 1–8 measures. The eligible professional would be required to report as many measures as are applicable to the eligible professional's practice. If reporting less than 9 measures covering 3 NQS domains, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures.

Comment: Some commenters provided general support for the option to report cross-cutting measures, as it may help bring alignment with respect to a set of measures all eligible professionals may report. However, most of these commenters believed that the reporting of cross-cutting measures should be voluntary, not mandatory. The majority of commenters opposed our proposal to require an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the proposed cross-cutting measure set specified in Table 52 (78 FR 40395). Some of these commenters believed that the proposed requirement is unfair, as the requirement to report on at least 2 cross-cutting measures placed an additional burden on certain specialists, such as those that do not provide primary care services, and not

on others. Other commenters emphasized that the cross-cutting measures did not apply to many specialty practices. Contrary to these commenters, some commenters expressed support for this proposal. Some of those who supported, this proposal, however, recommended a more phased-in approach to the reporting of cross-cutting measures. One of these commenters recommended that the proposal be amended to require only the reporting of 1 measure in the cross-cutting measure set. Some of these commenters were confused as to whether this proposal would increase the proposed number of measures to be reported to 11 measures.

Response: With respect to the commenters' concerns that requiring reporting of at least 2 cross-cutting measures for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter, we understand that the cross-cutting measures we are finalizing in Table 52 are limited and should only apply to certain eligible professionals for which the measures apply. We believe we sufficiently exclude eligible professionals for which the cross-cutting measures do not apply by only proposing this requirement for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter. We believe our interest in collecting data that are more varied to better capture the overall quality of care provided to patients as well as our desire to create a core set of measures for PQRS outweighs this concern. In the future, we will consider adding to this cross-cutting measures set so that more professionals that are eligible may be able to participate in the reporting of a core set of measures. With respect to the commenters who expressed concern that the proposed measures in the proposed cross-cutting measures set did not apply to many specialties, we note that an eligible professional would not be required to report on the measures contained in the cross-cutting measures set if none of the measures applied to the eligible professional's practice. With respect to taking a more phased-in approach to introducing the cross-cutting measure set, for the 2017 PQRS payment adjustment, we agree with these commenters and will therefore phase-in the requirement to report on cross-cutting measures by only requiring the reporting of 1 cross-cutting measure. We do note, however, that we believe that requiring the reporting of 2 measures in the cross-cutting measures set is not overly burdensome. Rather, we believe it helps eligible professionals narrow the choices of measures for which to report in the PQRS measure set. Regardless, we understand the commenters' concerns regarding the need for a gradual phase

in of the cross-cutting measure set. Therefore, based on the comments received and for the reasons stated above and in the proposed rule, we are modifying our proposal to require that an eligible professional who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period report at least 1 measure contained in the cross-cutting measure set we are finalizing specified in Table 52. Please note that it is our intention to move towards requiring the reporting of more cross-cutting measures in the future.

Please also note that this does not bring the total number of measures required to be reported under this criterion to 10 measures. Rather, if an eligible professional sees at least 1 Medicare patient in a face-to-face encounter during the 12-month PQRS payment adjustment reporting period, 1 of the 9 measures the eligible professional reports must be measures contained in the cross-cutting measure set. Therefore, an eligible professional would report at least 1 cross-cutting measure and 8 additional PQRS measures covering 3 NQS domains.

In the instance where an eligible professional may not have at least 9 measures applicable to his/her practice, the eligible professional would still be required to report at least 1 cross-cutting measure, if applicable. As we noted, we believe we sufficiently exclude eligible professionals for which the cross-cutting measures do not apply by only proposing this requirement for eligible professionals who see at least 1 Medicare patient in a face-to-face encounter.

Comment: One commenter believes that the threshold of seeing 1 Medicare patient in a face-to-face encounter for the requirement to report on cross-cutting measures is too low. The commenter was concerned that this would further burden eligible professionals who rarely see Medicare patients.

Response: We understand the commenter's concern. However, as we believe in the importance of the cross-cutting measures set we are finalizing in Table 52, it is our desire to encourage reporting of the measures contained in the cross-cutting measures set when applicable. We proposed this threshold to exclude certain specialties that do not see Medicare patients. However, we expect those eligible professionals who see Medicare patients to report on the cross-cutting measures we specify in Table 52.

Comment: One commenter sought clarification on the definition of a face-to-face encounter by specifying which codes apply to this definition and urged that procedural encounters not be included in the list of face-to-face encounters.

Response: As we stated in the proposed rule, we will determine whether an eligible professional had a ''face-to-face'' encounter by seeing whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional 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 requirements to report at least 1 cross-cutting measure specified in Table 52 (79 FR 40395 through 40396). While we will not provide the specific codes for what we define as a "face-to-face" encounter here, we will provide the codes and any additional guidance on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via claims or registry 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. The commenters noted that, particularly for those eligible professionals who see many patients, requiring the reporting of quality measures for more than 50 percent of the eligible professional's Medicare Part B FFS patients is burdensome.

Response: We understand this concern, particularly with those eligible professionals who see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We believe that the 50 percent threshold provides us with an adequate sample to properly determine the quality of care provided. We also believe that requiring that an eligible professional report on at least 50 percent of his/her Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where eligible professionals are still becoming accustomed to PQRS reporting. Based on the comments received

and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via claims or registry 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.

Comment: Some commenters generally supported the MAV process. However, some commenters expressed the need to clarify the MAV process for both claims and registry as well as to provide greater transparency in this process.

Response: We understand the need to further clarify the MAV process for both claims and registry, as well as to provide transparency in this process. We believe the 2015 MAV process that we proposed for the 2017 PQRS payment adjustment is transparent, as it is very similar to the 2014 MAV process that we finalized for the 2014 PQRS incentive and 2016 PQRS payment adjustment, for which we have already provided detailed technical guidance. Specifically, we have made education and outreach documents, as well as the MAV measure clusters, (that is, sets of measures that determine when other measures could have been reported and therefore trigger use of the MAV process), available for the 2014 MAV process at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html, and we will update these materials as necessary for the 2015 MAV process. Please note that, as the MAV process evolves, we expect to be able to provide further guidance to aid eligible professionals in understanding the MAV process. We will post additional clarifying information, including a document explaining the MAV process for 2015, on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html. We believe that posting this guidance as we have in years prior provides adequate transparency in this process. Moreover, should an eligible professional have further questions regarding the MAV process, he or she may contact our QualityNet Help Desk for more information. The contact information for the Help Desk can be found here: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/HelpDeskSupport.html.

After reviewing the comments, we are finalizing our proposal to modify §414.90(j) and finalize the following criterion for individual eligible professionals reporting via claims and registry:

For the 12-month reporting period for the 2017 PQRS payment adjustment, 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 specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), 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.

We understand that there may be instances where an eligible professional may not have at least 9 measures applicable to an eligible professional's practice. In this instance, an eligible professional reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the eligible professional reports on 1-8 measures, as applicable, to the eligible professional's practice. If an eligible professional reports on 1-8 measures, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we will implement for claims and registry for the 2017 PQRS payment adjustment is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive. For more information on the claims MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. 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.

b. Criterion for Satisfactory Reporting of Individual Quality Measures via EHR for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2013 PFS final rule with comment period, we finalized the following criterion for the satisfactory reporting for individual eligible professionals reporting individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2014 PQRS incentive: Report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT 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 (see Table 47 at 78 FR 74479).

To be consistent with the criterion we finalized for the 2014 PQRS incentive, 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 modify §414.90(j) and proposed the following criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment: The eligible professional would report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT 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.

We solicited public comment on this proposal.

The following is summary of the comments we received regarding our proposed criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a lower reporting threshold for those eligible professionals practicing in specialties for which few PQRS measures exist.

Response: We understand the commenters' concerns. We note that we addressed these comments related to the reporting of 9 measures covering 3 domains as it relates to reporting via claims and registry above in section III.K.1.a., and that explanation also applies here with reporting via a direct EHR product that is CEHRT or EHR data submission vendor product that is CEHRT. Furthermore, we believe that aligning our EHR reporting options with the CQM component of meaningful use under the EHR Incentive Program actually reduces burden on eligible professionals when reporting. For the reasons explained above and to be consistent with the criterion we are finalizing for claims and registry as well as to be consistent with the requirements to meet the CQM component of meaningful use under the EHR Incentive Program, we are finalizing this proposal.

After reviewing the comments, we are finalizing our proposal as proposed to modify §414.90(j) and to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report individual measures via a direct EHR product that is CEHRT or an EHR data submission vendor product that is CEHRT for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT 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.

c. Criterion for Satisfactory Reporting of Measures Groups via Registry for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2013 PFS final rule with comment period, we finalized the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the

2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, 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 (see Table 47 at 78 FR 74479).

To be consistent with the criterion we finalized for the 2014 PQRS incentive, we proposed to modify §414.90(j) to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional 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.

Although we proposed a satisfactory reporting criterion for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment that is consistent with criterion finalized for the 2014 PQRS incentive, please note that in section III.K of this final rule with comment period, we are changing the definition of a PQRS measures group.

We solicited but received no public comment on our proposed satisfactory reporting criterion for individual eligible professionals reporting measures groups via registry for the 2017 PQRS payment adjustment. Therefore, we are finalizing our proposal as proposed to modify §414.90(j) to indicate the following criterion for the satisfactory reporting for individual eligible professionals to report measures groups via registry for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, 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.

3. Satisfactory Participation in a QCDR by Individual Eligible Professionals

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 eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a QCDR.

a. Criterion for the Satisfactory Participation for Individual Eligible Professionals in a QCDR for the 2017 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional 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 eligible professional is satisfactorily participating in a QCDR for the year. "Satisfactory participation" is a new standard under the PQRS and is a substitute for the underlying standard of "satisfactory reporting" data on covered professional services that eligible professionals must meet to avoid the PQRS payment adjustment. Currently, §414.90(e)(2) states that individual eligible professionals must be treated as satisfactorily reporting data on quality measures if the individual eligible professional satisfactorily participates in a QCDR.

In the CY 2014 PFS final rule with comment period, although we finalized satisfactory participation criteria for the 2016 PQRS payment adjustment that are less stringent than the satisfactory participation criteria we finalized for the 2014 PQRS incentive, we noted that it was "our intention to fully move towards the reporting of 9 measures covering at least 3 domains to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment" (78 FR 74477). Specifically, we finalized the following two criteria for the satisfactory participation in a QCDR for the 2014 PQRS incentive at §414.90(i)(3): For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the QCDR covering at least 3 of the NQS domains, <u>and</u> report each measure for at

least 50 percent of the eligible professional's applicable patients. Of the measures reported via a QCDR, the eligible professional must report on at least 1 outcome measure.

To be consistent with the number of measures reported for the satisfactory participation criterion we finalized for the 2014 PQRS incentive, for purposes of the 2017 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2015), we proposed to modify §414.90(k) to add the following criteria for individual eligible professionals to satisfactorily participate in a QCDR for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the eligible professional 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 eligible professional's patients. Of these measures, the eligible professional would 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.

Unlike the satisfactory participation criteria that were established for the 2014 PQRS incentive, we proposed to modify §414.90(k)(4) to require that an eligible professional report on not only 1 but at least 3 outcome measures (or, 2 outcome measures and at least 1 resource use, patient experience of care, or efficiency/appropriate use if 3 outcomes measures are not available). We proposed this increase because it is our goal to, when appropriate, move towards the reporting of more outcome measures. We believe the reporting of outcome measures (for example, unplanned hospital readmission after a procedure) better captures the quality of care an eligible professional provides than, for example, process measures (for example, whether a Hemoglobin A1c test was performed for diabetic patients). In establishing this proposal, we understood that a QCDR may not have 3 outcomes measures within its quality measure data set. Therefore, as an alternative to a third outcome measure, we proposed to allow an eligible professional to report on at least 1 resource use, patient experience of care, or efficiency/appropriate use measure in lieu of an outcome measure.

We solicited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: Commenters generally urged more flexibility in allowing QCDRs to determine reporting criteria under this option.

Response: While we agree that QCDRs should generally be given some flexibility when participating in the PQRS, we do not agree that QCDRs be given flexibility in determining reporting criteria. We believe it is necessary to have consistent reporting criteria, so that quality measures data on eligible professionals may be more easily compared for purposes of other programs that use PQRS quality data to rate and compare eligible professionals, such as the VM.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Commenters also noted that certain eligible professionals do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures.

Response: While we understand the commenters' concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare to reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for satisfactory participation for the 2016 PQRS payment adjustment via a QCDR that aligned with the criteria we finalized for the 2014 PQRS incentive: For the 12-month 2016 PQRS payment adjustment reporting period, report at least 9 measures covering at least 3 NQS domains AND report each measure for at least 50 percent of the applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. Of the measures reported via a QCDR, the eligible professional must report on at least 1 outcome measure (78 FR 74478). Additionally, in the CY 2014 PFS final rule, we noted that "it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive" (78 FR 74465). We believe that establishing criteria for the satisfactory reporting of the 2017 PQRS payment adjustment that are consistent with these proposed criteria as well as signaling our intent to ramp up the satisfactory reporting

criteria provided enough advance notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Based on the comments received and for the reasons stated, we are finalizing our proposal for QCDRs to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via a QCDR report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. The commenters noted that, particularly for those eligible professionals who see many patients, requiring the reporting of quality measures for more than 50 percent of the eligible professional's patients is an enormous burden.

Response: We understand this concern, particularly with respect to those eligible professionals who see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We also believe that requiring that an eligible professional report on at least 50 percent of his/her Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where eligible professionals are still becoming accustomed to PQRS reporting. Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment, an eligible professional reporting individual measures via a QCDR report each measure for at least 50 percent of the eligible professional's patients seen during the reporting period to which the measure applies. Please note that, unlike the claims and registry-based reporting mechanisms, if using a QCDR, an eligible professional must report on ALL (Medicare and non-Medicare) patients.

Comment: The majority of commenters opposed our proposal to report on at least 3 outcome measures, as many of these commenters believed QCDRs might not have 3 outcome measures available

to report. The commenters urged a more gradual approach to the reporting of outcome measures via a QCDR.

Response: We understand the commenters' concerns. To accommodate these concerns, we are modifying this proposal to require only reporting of 2 outcome measures or, if 2 outcome measures are not available, report on 1 outcome measure and 1 of the following types of measures – resource use, patient experience of care, efficiency/appropriate use or patient safety. We believe this compromise still raises the bar on the types of measures eligible professionals must report, but allows QCDRs that may only have 1 outcome measure available to still qualify and participate in the PQRS. We note, however, our intention to increase the number of outcome measures that must be reported in the future.

In addition, we note that we are adding another category – patient safety – of measures that an eligible professional may report in lieu of an outcome measure. While we did not include this category before, we believe the addition of the patient safety category is appropriate, as we believe that it is equally important to measure patient safety, as it is to measure resource use, patient experience of care, or appropriate use. Furthermore, we believe the addition of another category of measures that may be reported in lieu of an outcome measure benefits eligible professionals and QCDRs and is responsive to some of the commenters' concerns regarding having enough measures to report, as it provides more options in terms of the measures an eligible professional may report in lieu of an outcome measure. We define the term "patient safety" as it applies to QCDRs in the QCDR measure section in III.K.6 below.

As a result of the comments, we are revising our proposal to modify §414.90(k) to indicate the following criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, 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, the eligible professional 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.

4. Criteria for Satisfactory Reporting for Group Practices Selected to Participate in the Group Practice Reporting Option (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 eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures. Accordingly, this section III.K.4 contains our satisfactory reporting criteria for group practices selected to participate in the GPRO. Please note that, for a group practice to participate in the PQRS GPRO in lieu of participating as individual eligible professionals, 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. Criteria for Satisfactory Reporting on PQRS Quality Measures Via the GPRO Web Interface for the 2017 PQRS Payment Adjustment

Consistent with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we proposed to modify §414.90(j) to incorporate the following criterion 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 2017 PQRS payment adjustment using the GPRO web interface for groups practices of 25–99 eligible professionals: 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 eligible professionals. 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 for which there is Medicare patient data.

In addition, we proposed to modify §414.90(j) to incorporate the following criteria for the satisfactory reporting of PQRS quality measures for group practices that registered to participate in the GPRO for the 12-month reporting period for the 2017 PQRS payment adjustment using the GPRO web interface for groups practices of 100 or more eligible professionals: The group practice would report all CAHPS for PQRS survey measures via a certified survey vendor. In addition, the group practice would report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

To maintain consistency in this reporting criteria, we note that this criteria is similar to the criterion we finalized for the satisfactory reporting of PQRS quality measures for group practices selected to participate in the GPRO for the 12-month reporting periods for the 2013 and 2014 PQRS incentives for group practices of 100 or more eligible professionals in the CY 2013 PFS final rule with comment period (see Table 49 at 78 FR 74486). However, we proposed to reduce the patient sample size on which a group practice is required to report quality measures data from 411 to 248. We examined the sample size of this reporting criterion and determined that the sample size we proposed reduces provider reporting burden while still allowing for statistically valid and reliable performance results. For the 25-99 sized groups reporting via the web interface, we recognized the proposal to move from reporting 218 to 248 patients per sample represents a slight increase in reporting. However, based on experience with the 218 count and subsequent statistical analysis, we believe that there are increased performance reliabilities and validities gained when changing the minimum reporting requirement to 248. We believe statistical reliability and validity is extremely important when measuring provider performance, particularly given the implications of the Physician VM and Physician Compare public reporting, discussed in section III.N

and section III.J respectively. Therefore, we believe this criterion improves on the criterion previously finalized.

For assignment of patients for group practices reporting via the GPRO web interface, in previous years, we have aligned with the Medicare Shared Savings Program methodology of beneficiary assignment (see 77 FR 69195). We note that, in section III.N. of the CY 2015 PFS proposed rule, we proposed to use a beneficiary attribution methodology for the VM for the claims-based quality measures and cost measures that is slightly different from the Medicare Shared Savings Program methodology, namely (1) eliminating the primary care service pre-step that is statutorily required for the Shared Savings Program and (2) including NPs, PA, and CNSs in step 1 rather than in step 2 of the attribution process. We believe that aligning with the VM's proposed method of attribution is appropriate, as the VM is directly tied to participation in the PQRS. Therefore, to achieve further alignment with the VM and for the reasons proposed in section III.N., we proposed to adopt the attribution methodology changes proposed for the VM into the GPRO web interface beneficiary assignment methodology. We invited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: A majority of the commenters supported our proposal for a group practice of 25 or more eligible professionals using the GPRO web interface to report on a patient sample of 248. With respect to having group practices of 100 or more eligible professionals report on a patient sample of 248 in lieu of 411 (the required patient sample for group practices of 100 or more eligible professionals for the 2014 PQRS incentive), the commenters agreed that this would reduce the reporting burden while still ensuring statistically valid and reliable performance results.

Response: We appreciate the commenters' feedback. Based on the positive comments received and for the reasons stated in the proposed rule, we are finalizing this proposal. Therefore, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for a group practice of 25 or more eligible professionals using the GPRO web interface, a group practice would be required to report on at least 248 patients.

As a result of the comments, we are finalizing the following criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25 to 99 eligible professionals using the GPRO web interface: report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 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.

In addition, we note that, in the past, we have not provided guidance on those group practices that choose the GPRO web interface to report PQRS quality measures but have seen no Medicare patients for which the GPRO measures are applicable, or if they have no (that is, 0 percent) responses for a particular module or measure. Since we are moving solely towards the implementation of PQRS payment adjustments, we sought to clarify this scenario here. If a group practice has no Medicare patients for which any of the GPRO measures are applicable, the group practice will not meet the criteria for satisfactory reporting using the GPRO web interface. Therefore, to meet the criteria for satisfactory reporting using the GPRO web interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable GPRO web interface measures (specified in Table 52). If a group practice does not typically see Medicare patients for which the GPRO web interface measures are applicable, we advise the group practice to participate in the PQRS via another reporting mechanism.

Please note that the discussion in this section III.K.4.a is limited to the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25-99 eligible professionals who register to participate in the GPRO and who have at least 1 Medicare patient for which any of the GPRO measures are applicable. As we discuss in greater detail in section III.K.4 below, since

we are requiring that group practices report on CAHPS for PQRS, the final criteria for group practices comprised of 100 or more eligible professionals are addressed in section III.K.4.c .

b. Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via Registry and EHR for the 2017 PQRS Payment Adjustment

For registry reporting in the GPRO, in the CY 2014 PFS final rule with comment period (see Table 49 at 78 FR 74486), we finalized the following satisfactory reporting criteria for the submission of individual quality measures via registry for group practices comprised of 2 or more eligible professionals in the GPRO for the 2014 PQRS incentive: 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 1—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. Measures with a 0 percent performance rate would not be counted. In the CY 2014 PFS final rule with comment period, we signaled that it was "our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive" (78 FR 74465).

Consistent with the criterion finalized for the 2014 PQRS incentive and the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using a qualified registry, we modified §414.90(j) to include the following satisfactory reporting criterion via qualified registry for ALL group practices who select to participate in the GPRO for the 2017 PQRS payment adjustment: The group practice would 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 2 measures in the cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply to the eligible professional, the group practice would 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 eligible professional'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.

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 2014 PQRS incentive (see Table 49 at 78 FR 74486), 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 as many measures as are 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. Please note that this MAV process does not apply to the application of the cross-cutting measure reporting requirement, as we require that all group practices report on at least 1 cross-cutting measure if an eligible professional in the group practice see at least sees at least 1 Medicare patient in a face-to-face encounter. The MAV process we proposed to implement for registry reporting is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive. 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.

For EHR reporting, consistent with the criterion finalized for the 2014 PQRS incentive 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 modify §414.90(j) to indicate the following satisfactory reporting criterion via a direct EHR product that is CEHRT or an EHR data submission vendor that is CEHRT for ALL group practices who select to participate in the GPRO for the 2017 PQRS payment adjustment: For the 12-month reporting period for the 2017 PQRS payment adjustment, the group practice would report 9 measures covering at least 3 domains. If the group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data. We invited public

comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: The majority of commenters opposed our proposal to require the reporting of 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Some commenters supported the reporting of 9 measures when using the EHR reporting mechanisms, indicating that the proposed criterion aligns with the criterion for meeting the eCQM component of meaningful use under the EHR Incentive Program. Some of the commenters opposing this proposal noted that group practices have been successful at meeting the criteria for satisfactory reporting for the PQRS incentives and payment adjustments in the past by reporting 3 measures, and increasing the number of measures to be reported would make it more difficult for these group practices to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. Other commenters also noted that certain group practices do not have 9 measures covering 3 NQS domains to report. For these reasons, some commenters suggested a more gradual approach to requiring the reporting of at least 9 measures covering 3 NQS domains, such as requiring the reporting of 5 or 6 measures rather than 9 measures. A few commenters also recommended establishing a lower reporting threshold for those group practices practicing in specialties for which few PQRS measures exist.

Response: While we understand the commenters concerns related to requiring the reporting of 9 measures covering up to 3 NQS domains, we believe we provided the public with adequate time to prepare to reporting criteria that requires the reporting of 9 measures. For example, we finalized criteria for the satisfactory reporting for the 2016 PQRS payment adjustment via registry that only required the reporting of 3 measures covering 1 NQS domain (see Table 50 at 78 FR 74486). However, we also finalized criteria for the 2016 PQRS payment adjustment using the registry- and EHR-based reporting mechanisms that aligned with the criteria we finalized for the 2014 PQRS incentive that generally required reporting of at least 9 measures covering at least 3 NQS domains. Additionally, in the CY 2014 PFS final rule, we noted that "it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive" (78 FR 74465). We believe that establishing criteria for the satisfactory

reporting of the 2016 PQRS payment adjustment that are consistent with this proposed criteria, as well as signaling our intent to ramp up the satisfactory reporting criteria, provided enough advanced notice to encourage eligible professionals to prepare to report 9 measures to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, with respect to those commenters concerned that a group practice may not have 9 measures covering at least 3 NQS domains applicable to his or her practice, in the proposed rule, with respect to reporting via registry, we noted that "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 2014 PQRS incentive (see Table 49 at 78 FR 74486), 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 as many measures as are applicable to the group practice's practice" (79 FR 40399). Under this proposed criterion for satisfactory reporting for the 2017 PQRS payment adjustment for group practices reporting via registry, a group practice who does not have at least 9 measures covering at least 3 NQS domains applicable to the practice may still meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment provided that the group practice reports all measures as are applicable to his or her practice.

With respect to reporting via an EHR, we noted that if the group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require the reporting of 9 measures covering at least 3 NQS domains via registry and EHR to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Commenters provided the same comments for requiring the reporting of cross-cutting measures for group practice reporting as individual reporting in section III.K.2.a. Some commenters provided general support for the option to report cross-cutting measures via registry, as it may help bring alignment with respect to a set of measures all group practices may report. However, most of these

commenters believed that the reporting of cross-cutting measures should be voluntary, not mandatory. The majority of commenters opposed our proposal to require a group practice that sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period to report at least 2 measures contained in the proposed cross-cutting measure set specified in Table 21 of the CY 2015 PFS proposed rule (79 FR 40395). Some of these commenters believed the proposed requirement to be unfair, as the requirement to report on at least 2 cross-cutting measures placed an additional burden on certain specialists and not others. Other commenters emphasized that the cross-cutting measures did not apply to many specialty practices. Contrary to these commenters, some commenters expressed support for this proposal. Some of those who supported, this proposal, however, recommended a more phased-in approach to the reporting of cross-cutting measures. One of these commenters recommended that the proposal be amended to require only the reporting of 1 measure in the cross-cutting measure set. Some of these commenters were confused as to whether this proposal would increase the proposed number of measures to be reported to 11 measures.

Response: Please note that our responses to these comments are the same responses we provided previously regarding our proposal to require the reporting of cross-cutting measures for individual reporting. Therefore, based on the comments received and for the reasons stated previously and in the proposed rule, we are modifying our proposal to require that a group practice who sees at least 1 Medicare patient in a face-to-face encounter during the 12-month 2017 PQRS payment adjustment reporting period report at least 1 measure contained in the cross-cutting measure set we are finalizing specified in Table 52.

Please note that this does not bring the total number of measures required to be reported under this criterion to 10 measures. Rather, if a group practice sees at least 1 Medicare patient in a face-to-face encounter during the 12-month PQRS payment adjustment reporting period, 1 of the 9 measures the group practice reports must be measures contained in the cross-cutting measure set. Therefore, a group practice would report at least 1 cross-cutting measure and 8 additional PQRS measures.

In the instance where a group practice may not have at least 9 measures applicable to his/her practice, the eligible professional would still be required to report at least 1 cross-cutting measure, if

applicable. If a group practice reporting on less than 9 measures does not have at least 1 cross-cutting measure applicable to his or her practice, then the group practice would report on as many measures as our applicable to his or her practice.

Comment: One commenter believes that the threshold of seeing 1 Medicare patient in a face-to-face encounter for the requirement to report on cross-cutting measures is too low. The commenter was concerned that this would further burden group practices who rarely see Medicare patients.

Response: We understand the commenter's concern. However, as we believe in the importance of the cross-cutting measures set we are finalizing in Table 52, it is our desire to encourage reporting of the measures contained in the cross-cutting measures set when applicable. We proposed this threshold to exclude certain specialties that do not see Medicare patients. However, we expect those group practices that see Medicare patients to report on the cross-cutting measures we specify in Table 52.

Comment: One commenter sought clarification on the definition of a face-to-face encounter by specifying which codes apply to this definition and urged that procedural encounters not be included in the list of face-to-face encounters.

Response: As we stated in the proposed rule, we will determine whether an eligible professional in a group practice had a ''face-to-face'' encounter by seeing whether the eligible professional billed for services under the PFS that are associated with face-to-face encounters, such as whether an eligible professional 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 proposals requiring reporting of at least 2 cross-cutting measures specified in Table 52. While we will not provide the specific codes for what we definite as a "face-to-face" encounter here, we will provide additional guidance on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

Comment: Some commenters opposed our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice reporting individual measures via registry 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. The commenters noted that,

particularly for those group practices that see many patients, requiring the reporting of quality measures for more than 50 percent of the group practice's Medicare Part B FFS patients is an enormous burden.

Response: We understand this concern, particularly with those group practices that see a large number of patients. However, it is important to collect sufficient quality measures data to ensure an adequate sample. We also believe that requiring that a group practice report on at least 50 percent of its Medicare Part B FFS patients helps to prevent potential selection bias that could skew the representation of quality of care; while the potential for selection bias still remains, we were mindful of concerns about provider burden during this period where group practices are still becoming accustomed to PQRS reporting. Based on the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to require that, to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice reporting individual measures via registry 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.

Comment: Some commenters generally supported the MAV process. However, some commenters expressed the need to clarify the MAV process for registry as well as to provide greater transparency in this process.

Response: We understand the need to clarify further the MAV process for both claims and registry. Please note that, as the MAV process evolves, we expect to be able to provide further guidance to aid group practices in understanding the MAV process. We will post additional clarifying information, including a "made simple" document on the MAV process for 2015 on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html. We believe that posting this guidance as we have in years prior provides adequate transparency in this process. Moreover, should a group practice have further questions regarding the MAV process, he/she may contact our QualityNet Help Desk for more information. The contact information for the Help Desk can be found here: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/HelpDeskSupport.html.

Because of the comments, we are finalizing our proposal to modify §414.90(j) and finalize the following criteria for satisfactory reporting for group practices participating in the GPRO via registry and EHR for the 2017 PQRS payment adjustment:

For group practices comprised of 2-99 eligible professionals reporting for the 12-month reporting period for the 2017 PQRS payment adjustment via 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 cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would 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'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.

We understand that there may be instances where a group practice may not have at least 9 measures applicable to an eligible professional's practice. In this instance, a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the group practice reports on 1-8 measures, as applicable, to the group's practice. If a group practice reports on 1-8 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. In addition, the MAV will also allow us to determine whether a group practice should have reported on any of the cross-cutting measures specified in Table 52. The MAV process we will implement for claims and registry for the 2017 PQRS payment adjustment is the same process that was established for reporting periods occurring in 2014 for the 2014 PQRS incentive. For more information on the claims MAV process, please visit http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. 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.

For group practices comprised of 2-99 eligible professionals reporting for the 12-month reporting period for the 2017 PQRS payment adjustment via EHR: report 9 measures covering at least 3 domains. If the group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

Please note that the discussion in this section III.K.4.b is limited to the criteria for the satisfactory reporting of group practices registered to participate in the GPRO for the 2017 PQRS payment adjustment using the EHR-based reporting mechanism to group practices comprised of 2-99 eligible professionals. The final criteria for group practices comprised of 100 or more eligible professionals are addressed in section III.K.1.c. following this section.

c. Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered to Participate in the GPRO via a CMS-Certified Survey Vendor for the 2017 PQRS Payment Adjustment

In the CY 2014 PFS final rule with comment period, we introduced satisfactory reporting criterion for the 2014 PQRS incentive related to reporting the CG CAHPS survey measures via a CMS-certified survey vendor (see Table 49 at 78 FR 74486). Consistent with the criterion finalized for the 2014 PQRS incentive and the group practice reporting requirements under section 1848(m)(3)(C) of the Act, we proposed 3 options (of which a group practice would be able to select 1 out of the 3 options) for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 25 or more eligible professionals (79 FR 40399).

Furthermore, as was required for group practices reporting via the GPRO web interface for the reporting periods occurring in 2014 (78 FR 74485), we proposed that all group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO, regardless of the reporting mechanism the group practice chooses, would be required to select a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. As such, for purposes of meeting the criteria for satisfactory reporting for the 2017 PQRS payment adjustment, a group practice participating in the PQRS GPRO would be required to use 1 of these 3 proposed reporting options mentioned above (that

is, GPRO web interface, qualified registry or EHR). We noted that, for reporting periods occurring in 2014, we stated that we would administer and fund the collection of (CG-CAHPS) data for these groups (of 100 or more eligible professionals using the GPRO web interface that are required to report on CAHPS for PQRS survey measures) (78 FR 74452). We stated that we would bear the cost of administering the CAHPS for PQRS survey measures, as we were requiring the group practices to report on CAHPS for PQRS survey measures. Unfortunately, beginning in 2015, it will no longer be feasible for us to continue to bear the cost of group practices of 100 or more eligible professionals to report the CAHPS for PQRS survey measures. Therefore, the group practice would be required to bear the cost of administering the CAHPS for PQRS survey measures.

However, as CAHPS for PQRS was optional for group practices comprised of 25-99 eligible professionals in 2014 (78 FR 74485) and whereas we proposed to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals, we proposed that CAHPS for PQRS would be optional for groups of 25-99 and 2-24 eligible professionals. We noted that all group practices that would be required to report or voluntarily elect to report CAHPS for PQRS would need to select and pay a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf.

We invited public comment on these proposals related to our proposals to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO as well as our proposal making the reporting of CAHPS for PQRS optional for group practices comprised of 2-99 eligible professionals that registry to participate in the PQRS GPRO to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. The following is a summary of the comments we received regarding on these proposals.

Comment: Commenters supported the option to report CAHPS for PQRS, as long as reporting CAHPS for PQRS remained optional. The majority of commenters opposed our proposal to require group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO, regardless of the reporting mechanism the group practice chooses, to select a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. These commenters believe that this requirement was too burdensome, particularly because CMS is not bearing the cost of administering

the survey. Some of these commenters requested that CMS delay requiring the reporting of CAHPS for PQRS to the 2016 reporting period. Other commenters requested that CMS continue to bear the cost of administering the CAHPS for PQRS survey.

Response: While we understand the commenters' concerns regarding requiring the reporting of CAHPS for PQRS, group practices comprised of 100 or more eligible professionals participating in the GPRO web interface reporting option have had 2 years of experience reporting CAHPS for PQRS as they have been required to report CAHPS for PQRS for both the 2013 and 2014 PQRS incentive. Groups of 25-99 eligible professionals reporting via GPRO web interface, qualified registry or EHR and groups of 100 or more eligible professionals reporting via qualified registry or EHR had the option to report CAHPS for PQRS in 2014. We believe that 2 years is enough time to become familiar with how the survey is administered. Therefore, we believe it is reasonable to require group practices of 100 of more eligible professionals to report on CAHPS for PQRS. With respect to some commenters' concerns about the additional burden the proposal to require group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO to report CAHPS for PQRS places on these group practices, we understand that this proposed requirement could bring additional reporting burden on these larger group practices. We believe that the value of the information contained in the CAHPS for PQRS survey outweighs this concern. In addition, we note that large group practices tend to be more sophisticated than other group practices with respect to resources, and, as such, we believe that this mitigates any additional burden on group practices of 100 or more eligible professionals. Therefore, based on the reasons we state here and in the proposed rule, we are finalizing our proposal to require reporting of CAHPS for PQRS for group practices comprised of 100 or more eligible professionals that register to participate in the PQRS GPRO.

We are also finalizing our proposal to make the reporting of CAHPS for PQRS optional for group practices comprised of 2-99 eligible professionals that register to participate in the PQRS GPRO to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Furthermore, we understand the commenters' concerns regarding having the group practices bear the cost of administering the CAHPS for PQRS survey, particularly for those group practices who will be

required to report CAHPS for PQRS to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment. However, it is not feasible for us to continue to bear the cost of administering the CAHPS for PQRS survey. We believe that bearing the cost of the CAHPS for PQRS survey for 2013 and 2014 provided adequate time for group practices to become familiar with administering the CAHPS for PQRS survey as well as signaled our commitment to reporting of the CAHPS for PQRS survey into the future.

Because of the comments received, we are finalizing the following final criteria for satisfactory reporting for the 2017 PQRS payment adjustment for group practices comprised of 2 or more eligible professionals. The following options are voluntary ways to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment for groups comprised of 2-99 eligible professionals. However, group practices comprised of 100 or more eligible professionals that are registered to participate in the GPRO must select one of these options to meet the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Option 1 – Registry: If a group practice of 2 or more eligible professionals chooses to use a qualified registry, in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, 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 up to 5 measures. 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 specified in Table 52.

Consistent with the group practice reporting option solely using a qualified registry for the 2017 PQRS payment adjustment, we understand that there may be instances where a group practice may not have at least 6 measures applicable to a group practice's practice. In this instance, a group practice reporting on less than 6 measures would still be able to meet the satisfactory reporting criterion via

registry if the group practice reports on as many measures as are applicable to the group practice's practice, including the measures in the cross-cutting measure set specified in Table 52. If a group practice reports on less than 6 individual measures using the qualified registry reporting mechanism in conjunction with a CMS-certified survey vendor to report CAHPS for PQRS, 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. 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.

Option 2 – EHR: If a group practice of 2 or more eligible professionals chooses to use a direct EHR product that is CEHRT or EHR data submission vendor that is CEHRT in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, 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 that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. 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.

Option 3 – GPRO Web Interface: Alternatively, if a group practice of 25-99 eligible professionals chooses to use the GPRO web interface in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2017 PQRS payment adjustment, 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.

Tables 50 and 51 provide a summary of the final criteria for satisfactory reporting – or, in lieu of satisfactory reporting, satisfactory participation in a QCDR – for the 2017 PQRS payment adjustment for eligible professionals and group practices. As you can see below, there are a total of 5 individual reporting options and 9 group practice reporting options. Therefore, there are a total of 14 reporting options under the PQRS for purposes of meeting the criteria for satisfactory reporting – or, in lieu of satisfactory reporting, satisfactory participation in a QCDR – for the 2017 PQRS payment adjustment.

d. The Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS)

In addition to CAHPS for PQRS, we received comments last year supporting the inclusion of the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS). The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality, which are important from the patient's perspective and for which the patient is the best source of information. The survey asks patients to provide feedback on surgical care, surgeons, their staff, and anesthesia care. It assesses patients' experiences with surgical care in both the inpatient and outpatient settings by asking respondents about their experience before, during and after surgery. The commenters stated that the CG-CAHPS survey would not accurately reflect the care provided by single- or multispecialty surgical or anesthesia groups. The commenters noted that S-CAHPS has been tested by the same standards as CG-CAHPS and follows the same collection mechanism as the CG-CAHPS. We agree with the commenters on the importance of allowing for the administration of S-CAHPS reporting and wish to allow for reporting of S-CAHPS in the PQRS for reporting mechanisms other than the QCDR. However, at this time, due to the cost and time it would take to find vendors to collect S-CAHPS data, it is not technically feasible to implement the reporting of the S-CAHPS survey measures for the 2017 PQRS payment adjustment. In the CY 2015 PFS proposed rule (79 FR 40400), we solicited comments on how to allow for reporting of the S-CAHPS survey measures for the 2018 PQRS payment adjustment and beyond. In addition, we sought comments on how to allow for reporting of the S–CAHPS survey measures for the 2018 PQRS payment adjustment and beyond. The following is a summary of the comments we received on these proposal:

Comment: The majority of commenters supported the introduction of S-CAHPS in the PQRS. These commenters supported our proposal to allow the reporting of S-CAHPS via a QCDR, and other commenters requested that group practices be able to report S-CAHPS via a CMS-certified survey vendor, similar to the way CAHPS for PQRS is currently being reported under the PQRS. Other commenters expressed concerns on introducing S-CAHPS for the PQRS. One commenter stated that S-CAHPS does not adequately capture the patient and caregiver experience with all types of anesthesia professionals. Another commenter expressed concerns related to determining how to select patients for which to administer S-CAHPS. Commenters were also concerned with the financial burden of administering the S-CAHPS survey, and asked CMS to explore ways to fund the administration of the S-CAHPS survey.

Response: We appreciate the commenters' feedback. However, at this time, due to the cost and time it would take to find vendors to collect S-CAHPS data, it is not technically feasible to implement the reporting of the S-CAHPS survey measures for the 2017 or 2018 PQRS payment adjustments. We note, however, that if a QCDR wishes to administer the S-CAHPS as a non-PQRS measure for the 2017 or 2018 PQRS payment adjustments, we would allow the QCDR to do so. We will take these comments into consideration as we continue to work to introduce S-CAHPS in the PQRS measure set for future years.

TABLE 50: Summary of Requirements for the 2017 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, 2015)	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 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 specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), 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, 2015)	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 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 specified in Table 52. If less than 9 measures apply to the eligible professional, the eligible professional would report up to 8 measure(s), 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, 2015)	Individual Measures	Direct EHR Product or EHR Data Submission Vendor Product	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.
12-month (Jan 1– Dec 31, 2015)	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, 2015)	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 eligible professional's patients. Of these measures, the eligible professional 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 51: Summary of Requirements for the 2017 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, 2015)	25-99 eligible professionals	Individual GPRO Measures in the GPRO Web Interface	GPRO Web Interface	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 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.
12-month (Jan 1–Dec 31, 2015)	25-99 eligible professionals and100+ eligible professionals	Individual GPRO Measures in the GPRO Web Interface + CAHPS for PQRS	GPRO Web Interface + CMS-Certified Survey Vendor	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals	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 cross-cutting measure set specified in Table 52. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would 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's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2015)	2-99 eligible professionals and 100+ eligible professio	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 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 up to 5 measures. Of the

Reporting Period	Group Practice Size	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria
	nals			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 specified in Table 52.
12-month (Jan 1– Dec 31, 2015)	2-99 eligible professionals	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 the measures for which there is 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, 2015)	2-99 eligible professionals and 100+ eligible professionals	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 up to 5 measures. 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.

5. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2015 and Beyond for Individual Eligible Professionals and Group Practices

CMS undergoes an annual Call for Measures that solicits new 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 non-statutory criteria.

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual eligible professionals 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, such as the Ambulatory Quality Alliance (AQA). 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 eligible professionals 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 basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there need to be special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic 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 with respect to 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 Measure Applications Partnership (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 2014 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.
- CMS is not accepting claims-based-only reporting measures in this process.
- Measures that are outcome-based are preferred to clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that identify care coordination and communication.
- Measures that identify care coordination of patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

As a general matter, please note that the measure tables contained in this section III.K. may also contain discussions of comments we received related to proposed changes to the measures included in the quality performance standard under the Shared Savings Program.

a. PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our responses to our proposals related to the measures in the PQRS for 2015 and beyond. We classified all measures against six domains based on the NQS's six priorities, as follows:

(1) Patient Safety. These measures 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 measures 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 measures 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 measures reflect efforts to lower costs and to significantly improve outcomes and reduce errors. These are measures of cost, resource use and appropriate use of healthcare resources or inefficiencies in healthcare delivery.

Please note that the PQRS quality measure specifications for any given 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 2014 and beyond, please note that detailed measure specifications, including the measure's title, for the individual PQRS quality measures for 2013 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, and potentially subsequent years of the EHR Incentive Program for Eligible Professionals, we note that the measure titles for measures available for reporting via EHR may change. To the extent that the EHR Incentive Program for Eligible Professionals updates its measure titles to include version numbers (77 FR 13744), we will use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program for Eligible Professionals. 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 could be updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. We 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 so fundamentally change an endorsed measure 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 will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

CMS is 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 55, we proposed that certain measures be removed from the PQRS measure set due to the measure owner/developer indicating that it will not be able to maintain the measure. We noted that this proposal is contingent upon the measure owner/developer not being able to maintain the measure. Should we learn that a certain measure owner/developer 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 2017 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. In addition, if, after the display of this final rule with comment period, we discover additional measures within the current PQRS measure set that a measure owner/developer can no longer maintain, we proposed to remove these measures from reporting for the PQRS beginning in 2015. We will discuss any such instances in the PQRS measure tables below.

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 aid eligible professionals and group practices to determine what measures best fit their practice, and in collaboration with specialty societies, we are beginning to group our final measures available for reporting according to specialty. The current listing of our measures by specialty can be found on our 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 eligible professionals seeking to determine what measures to report. Eligible professionals are not required to report measures according to these suggested groups of measures. In addition to group measures according to specialty, we also plan to have a measure subset for measures that specifically addresses multiple chronic conditions. As measures are adopted or revised, we will continue to update these groups to reflect the measures available under the PQRS, as well as add more specialties.

In the CY 2014 PFS final rule with comment period, we stated that "unless there are errors discovered in updated electronic measure specifications, the PQRS intends to use the most recent, updated versions of electronically specified clinical quality measures for that year" (78 FR 74489). We proposed that, if we discovered errors in the most recently updated electronic measure specifications for a certain measure, we would use the version of electronic measure specifications that immediately precedes the most recently updated electronic measure specifications. Any such change to a measure is also described in the PQRS measure tables below.

Additionally, we noted that, with respect to the following e-measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), a substantive error was discovered in the June 2013 version of this electronically specified clinical quality measure. Therefore, the PQRS required the use of the prior, December 2012 version of this measure, which is CMS140v1 (78 FR 74489). Please note that, consistent with other EHR measures, since a more recent and corrected version of this measure has been developed, we will require the reporting of the most recent, updated versions of the measure Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387) – currently version CMS140v3 – for the year.

b. Cross-Cutting Measure Set for 2015 and Beyond

In accordance with our criteria for the satisfactory reporting of PQRS measures for the 2017 PQRS payment adjustment via claims and registry that requires an eligible professional or group practice to report on at least 2 cross-cutting measures, we proposed 18 cross-cutting measure set specified in Table 21 in the CY 2015 PFS proposed rule for 2015 and beyond (79 FR 40404). Please note that we are finalizing all measures as proposed (see Table 52). We are also adding a measure to the list of cross-cutting measures, based on comments that were submitted. Please note that our response and final decision for each of these measures is found in Table 52. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted. Please note that we are changing some of the reporting mechanisms available for certain cross-cutting measures in Table 52 from the reporting options we proposed would be available in the CY 2015 PFS proposed rule (79 FR 40404). To the extent that changes to the reporting mechanisms for the cross-cutting measures specified in Table 52 were made from what was specified in the proposed rule, we provide the explanation and rationale for those changes in Table 53.

The following are high-level comments regarding our proposals related to the proposed cross-cutting measure set:

Comment: Several commenters supported the development of a cross-cutting measure set as well as the composition as proposed, while other commenters were concerned about this new requirement noting the measures may not be as applicable to some specialists.

Response: With respect to the commenters who expressed concern that the proposed measures in the proposed cross-cutting measures set did not apply to many specialties, we note that limitations such as only requiring reporting of a cross-cutting measures in a face-to-face encounter would exclude those eligible professionals for which the measures do not apply. With respect to taking a more phased-in approach to introducing the cross-cutting measure set, please note that we have modified this proposal to only require the reporting of 1 cross-cutting measure. We believe that requiring the reporting of 1 measure in the cross-cutting measures set is not overly burdensome and may help eligible professionals by providing direction on what measures

to report. We are modifying our proposal to only require eligible professionals who see at least 1 Medicare patient in a face-to-face encounter to report on 1 cross-cutting measure.

TABLE 52: Individual Quality Cross-Cutting Measures for the PQRS to Be Available for Satisfactory Reporting Via Claims, Registry, and EHR Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed or with Modifications											
N/A /402	N/ A	Communit y/Populati on Health	**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 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 2015 PQRS.	NCQA / NCIQM			X			X	
N/A/ 400	N/ A	Effective Clinical Care	**Hepatitis C: 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 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 2015 PQRS.	AGA / AASLD / AMA-PCPI			X				
0097 /046	N/ A	Communi cation and Care Coordinati on	**Medication Reconciliation:** Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented This measure is reported as two rates	NCQA/ AMA-PCPI	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			stratified by age group: Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older. Commenters supported the inclusion of this measure as cross cutting "due to its focus on critical care coordination transitions between hospitals and ambulatory care providers." As such, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS. We note that while the proposed rule limited the applicability of this measure to patients 65 years and older, the range of this mesaure was changed to include patients 18-64 years of age by the measure steward. This measure update is endorsed by NQF.								
0326 /047	N/ A	Communi cation and Care Coordinati on	**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 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 2015 PQRS.	NCQA/ AMA-PCPI	X		X			X	
0041 /110	147 v4	Communit y/Populati on Health	**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 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 2015 PQRS.	AMA-PCPI	X		X	X	X	X	ACO MU2
0043 /111	127 v3	Communit y/Populati on Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA	X		X	X	X	X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			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 2015 PQRS.								
0421 /128	69v 3	Community/Population Health	**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/m^2; Age 18-64 years BMI ≥ 18.5 and < 25 kg/m^2 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 2015 PQRS.	CMS/QIP	X		X	X	X	X	ACO MU2
0419 /130	68v 4	Patient Safety	**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 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 2015 PQRS.	CMS/QIP	X		X	X	X	X	ACO MU2
0420 /131	N/ A	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to	CMS/QIP	X		X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			make this measure reportable as a cross-cutting measure for 2015 PQRS.								
0418 /134	2v4	Community/Population Health	**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 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 2015 PQRS.	CMS/QIP	X		X	X	X	X	ACO MU2
N/A /182	N/ A	Communication and Care Coordination	**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 No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.	CMS/QIP	X		X				
0028 /226	138 v3	Community/Population Health	**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 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 2015 PQRS.	AMA-PCPI	X		X	X	X	X	ACO MU2 Million Hearts

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0018 /236	165 v3	Effective Clinical Care	**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 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 2015 PQRS. This measure was part of the cardiovascular prevention and ischemic vascular disease measures group. Therefore, the details and rationale regarding the changes we are making to this measure can be found in our discussion of the cardiovascular prevention and ischemic vascular disease measures group in section III.K.5.d of this final rule.	NCQA	X		X	X	X		ACO MU2 Million Hearts
0038 /240	117 v3	Community/Population Health	**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 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 2015 PQRS.	NCQA				X			MU2
N/A /317	22v 3	Community/Population Health	**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 (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated 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 2015 PQRS.	CMS/QIP	X		X	X	X	X	ACO MU2 Million Hearts

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0101 /318	139 v3	Patient Safety	**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 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 2015 PQRS.	NCQA				X	X		ACO MU2
0005 &00 06 /321	N/ A	Person and Caregiver Experienc e and Outcomes	**CAHPS for PQRS Clinician/Group Survey:** • 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 No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.	AHRQ		X					ACO
N/A /374	50v 3	Communi cation and Care Coordinati on	**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 No comments were received regarding this measure being classified as cross-cutting. CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2015 PQRS.	CMS/BA H				X			MU2
Additional Measures Finalized in Response to Public Comment											
0059 /001	122 v3	Effective Clinical Care	**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 This measure was not proposed for the cross-cutting measure set for 2015 and beyond. However, in addition to seeking comment on the proposed cross-cutting	NCQA	X		X	X	X	X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			measure set specified in Table 21 of the proposed rule, we sought comment on other measures that commenters believed should be included in that proposed cross-cutting measure set for 2015 and beyond (79 FR 40403). Commenters suggested that CMS "include a diabetes-related measure such as NQF 0059 "Hemoglobin Al C Poor Control" or other diabetes measure in the cross-cutting measure set for reporting under PQRS" as it is a measure that most eligible professionals can report. CMS agrees and is, therefore, finalizing the addition of PQRS #001 to the cross-cutting measure set for 2015 PQRS. CMS may consider additional measures for the cross-cutting measure set in future program years.								

¥ 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 2015 and Beyond

Table 22 in the CY 2015 PFS proposed rule (79 FR 40410) contained the additional measures we proposed to include in the PQRS measure set for CY 2015 and beyond. In Table 53, we provide our response to the comments we received on these measures as well as our final decisions on these proposed measures. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted. As stated above, please note that the following tables may also contain discussions of comments we received related to proposed changes to the measures included in the quality performance standard under the Shared Savings Program.

TABLE 53: New Individual Quality Measures and Those Included in Measures Groups for the PQRS to Be Available for Satisfactory Reporting Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed or with Modifications											
1879/383	N/A	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** The percentage of individuals 18 years of age or greater as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who are prescribed an antipsychotic medication, with adherence to the antipsychotic medication [defined as a Proportion of Days Covered (PDC)] of at least 0.8 during the measurement period (12 consecutive months) Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through claims. Although CMS understands commenters' concern regarding reporting via registry only, we have determined that the complexity of the measure warrants reportability only through the registry reporting option. For this reason, CMS is finalizing this measure to be reportable beginning in 2015 for PQRS.	CMS / FMQAI			X				
N/A/384	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Repair Success Rate:** Percentage of surgeries for primary rhegmatogenous retinal detachment where the retina remains attached after only one surgery CMS received no comments on this measure. This is an outcome-based measure that addresses a new clinical concept not currently captured within PQRS and targets a specialty provider group, ophthalmologist, who are often underrepresented in the PQRS program. As such, this measure provides meaningful value for the PQRS program. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	American Association of Eye and Ear Centers of Excellence			X				
N/A/385	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery Success Rate:** Percentage of retinal detachment cases achieving flat retinas six months post-surgery Commenters disagreed with CMS's proposal to include this measure in PQRS, noting the measure has not been broadly	American Association of Eye and Ear Centers of Excellence/ The Australian Council			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			tested and possible unintended consequences that may drive physicians to perform retinal detachment surgeries in the hospital setting. This is an outcome-based measure that addresses a new clinical concept not currently captured within PQRS and targets a specialty provider group, ophthalmologists, who are often underrepresented in the PQRS program. Furthermore, the steward confirmed the setting of service is not relevant as a negative consequence of this measure. CMS agrees with this assessment that the setting of care is not an unintended consequence that would negatively impact the patient if this surgery were conducted in a hospital and believes this measure provides meaningful value for the PQRS program. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	on Healthcar e Standards							
N/ A /38 6	N/ A	Person and Caregiver-Centered Experience and Outcomes	**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 (for example, advance directives, invasive ventilation, hospice) at least once annually No comments were received regarding this measure being added to PQRS. CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	AAN			X				
N/ A /38 7	N/ A	Effective Clinical Care	**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 Although one commenter requested this measure be adjusted to include more than "injection drug use," citing its limiting risk factor, several commenters supported the inclusion of this measure in PQRS. Injection drug use has been associated as a high risk factor for HCV. Therefore, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	AGA / AASLD / PCPI			X				
N/ A /38 8	N/ A	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vsitrectomy):** Rupture of the posterior capsule during anterior segment surgery	AAEECE / ACHS			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			requiring vsitrectomy Several commenters submitted positive comments about the inclusion of this measure in the PQRS program and requested that CMS make this measure reportable via claims. In addition, there were commenters that encouraged CMS to "test this measure before implementation." Commenters did not specify the type of testing. This measure, per the guidelines of quality measure inclusion required for the PQRS program, has been tested by the steward. Furthermore, this is an outcome measure that complements the existing cataracts measures with a clinical focus not currently captured within PQRS. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry and measure group reporting only. CMS is moving away from claims-based reporting and as such is not finalizing this measure for claims reporting in 2015 PQRS.								
N/A /389	N/A	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients who achieve planned refraction within +-1,0 D Several commenters submitted positive comments about the inclusion of this measure in the PQRS program and requested that CMS make this measure reportable via claims. In addition, there were commenters that encouraged CMS to test this measure before implementation. Commenters did not specify the type of testing. This measure, per the guidelines of quality measure inclusion in the PQRS program, has been tested by the steward. Furthermore, this is an outcome measure that complements the existing cataracts measures with a clinical focus not currently captured within PQRS. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry and measure group reporting only. CMS is moving away from the claims reporting option and as such is not finalizing this measure as reportable for claims in 2015 PQRS.	AAEECE / ACHS			X			X	
N/A /390	N/A	Person and Caregiver-Centered Experience and	**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	AGA / AASLD / PCPI			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Outcomes	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 Some commenters expressed concern that this measure might incentivize providers not to treat patients, indicating a provider might "simply note "the patient expressed reservations about potential side effects and we decided to defer treatment," rather than working with the patient to address concerns and optimize uptake of the appropriate care." However, CMS feels strongly that patients need to be provided appropriate information that would help patients to make their decision on treatment options. This measure focuses on discussion and shared decision making on treatment options. For these reasons, CMS is finalizing its proposal to include this measure for registry and measure group reporting in 2015 PQRS.								
N/A /391	N/A	Communication and Care Coordination	**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: - 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 Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through claims. It is a priority for PQRS to ultimately increase the quality of health care. In order to achieve this goal, PQRS needs reliable and robust data on health service delivery and claims-based reporting has demonstrated, over	NCQA			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			several years, the highest error rate among the PQRS reporting options. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry reporting only.								
N/A /392	N/A	Patient Safety	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	HRS			X				
N/A /393	N/A	Patient Safety	**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 Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	HRS			X				
1407 /394	N/A	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	NCQA			X				
N/A /395	N/A	Communication and Care Coordination	**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 Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	CAP	X		X				
N/A /396	N/A	Communication and Care Coordination	**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 Commenters supported the inclusion of this	CAP	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								
N/A /397	N/A	Communication and Care Coordination	**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 Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	CAP	X		X				
N/A /398	N/A	Effective Clinical Care	**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 Several commenters disagreed with CMS's proposal to replace existing measure (PQRS #064 "Asthma: Assessment of Asthma Control – Ambulatory Care Setting") with this new measure. Details regarding commenters concerns with removing PQRS #064 can be found in Table 56. Although CMS understands the limitations of the current measure as it relates to the upper age limit, risk adjustment and the calculation of improvement over time, this measure represents a more robust clinical outcome for asthma care. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS for registry only. In addition, CMS re-evaluated the categorization of this measure to the Person and Caregiver Experience and Outcomes domain and determined it was more appropriately categorized under Effective Clinical Care. As such, CMS is finalizing this measure under Effective Clinical Care for 2015 PQRS program.	MNCM			X				
N/A /399	N/A	Effective Clinical Care	**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 Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	ACC-AHA			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/A/ /400	N/A	Effective Clinical Care	**Hepatitis C: 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 Although one commenter requested this measure be adjusted to include more than "injection drug use," citing its limiting risk factor, injection drug use has been associated as a high-risk factor for HCV. Additionally, the commenter suggested that this measure include "risk groups" to encompass men who have sex with men (MSM). Transmission of HCV by sex is low and does not necessitate routine screening. Furthermore, several commenters supported the inclusion of this measure in PQRS. CMS received public comment from the measure steward indicating this measure should be classified under the domain of Effective Clinical Care. After further review, CMS determined this measure was more appropriately categorized under the Effective Clinical Care domain based on the HHS decision rule guidelines for categorizing measures. For these reasons, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	AGA / AASLD / AMA-PCPI			X				
N/A /401	N/A	Effective Clinical Care	**Screening for Hepatocellular Carcinoma (HCC) in patients with Hepatitis C 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 Commenters supported the inclusion of this measure in PQRS, but also suggested CMS refine the measure language to include other risk groups and diagnosis. We appreciate the commenters' support for this measure. With respect to the measure language, we note that we have decided not to make changes to this measure in order to maintain consistency with the specifications maintained by the measure	AGA / AASLD / AMA-PCPI			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			developper and owner. Based on the comments received, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								
N/A /402	N/A	Community/ Population Health	**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 Commenters supported the inclusion of this measure in PQRS. For this reason, CMS is finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.	NCQA / NCIQM			X			X	
Measures Not Finalized as Proposed											
1880 /N/A	N/A	Patient Safety	**Adherence to Mood Stabilizers for Individuals with Bipolar I Disorder:** The measure calculates the percentage of individuals aged 18 years and older with bipolar I disorder who are prescribed a mood stabilizer medication, with adherence to the mood stabilizer medication [defined as a Proportion of Days Covered (PDC)] of at least 0.8 during the measurement period (12 consecutive months) Commenters supported the inclusion of this measure in PQRS but request this measure also be reportable through registry. CMS confirmed with the measure steward that this measure was tested for reportability through claims and not registry. Given this, CMS does not believe this measure is ready for implementation in 2015 PQRS as CMS does not believe this measure is appropriate for claims-based reporting and thus CMS is not finalizing this measure for reporting in 2015 PQRS.	CMS/FMQAI	X						
N/A /N/A	N/A	Person and Caregiver-Centered Experience and Outcomes	**Average change in functional status following lumbar spine fusion surgery:** Average change from pre-operative functional status assessment to one year (nine to fifteen months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool Commenters note this measure has not been fully vetted or tested. Furthermore, there are analytic challenges to implementing this measure and the lack of a performance target to assess this measure against. For this reason, CMS is not finalizing this measure for inclusion in 2015 PQRS.	MNCM			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/A /N/A	N/A	Efficiency and Cost Reduction	**Avoidance of inappropriate use of imaging for adult ED patients with traumatic low back pain:** Avoidance of inappropriate use of imaging for adult ED patients with traumatic low back pain While one commenter supported the addition of this measure to PQRS noting it "will incentivize providers to minimize unnecessary or excessive radiation exposure, which insures to the benefit of beneficiaries," the measure steward withdrew support of this measure as the measure is not yet sufficiently specified nor has it undergone public review and comment. For this reason, CMS is not finalizing this measure for PQRS 2015.	ACEP			X				
1885 /N/A	N/A	Person and Caregiver-Centered Experience and Outcomes	**Depression Response at Twelve Months-Progress Towards Remission:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 (Patient Health Questionnaire 9) score greater than nine who demonstrate a response to treatment at twelve months defined as a PHQ-9 score that is reduced by 50% or greater from the initial PHQ-9 score. This measure applies to both patients with newly diagnosed or existing depression identified during the defined measurement period whose current PHQ-9 score indicates a need for treatment CMS believes that NQF 1885 is duplicative of PQRS 370 "Depression Remission at Twelve Months." As such, CMS is not finalizing its proposal to add NQF 1885 as a new measure for reporting in the 2015 PQRS Program.	MNCM			X				
N/A /N/A	N/A	Patient Safety	**Discontinuation of Antiviral Therapy for Inadequate Viral Response:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C genotype 1 who had an inadequate response to antiviral treatment for whom antiviral treatment was discontinued Commenters, including the measure steward, suggest clinical guidelines are changing for Hepatitis C virus therapy, impacting the clinical appropriateness of this measure specifically. No other measures under consideration were affected. As such, CMS is not finalizing this measure for PQRS 2015, allowing time for the evolving clinical guidance to be finalized.	AGA / AASLD / PCPI			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
N/A /N/A	N/A	Effective Clinical Care	**Freedom from Reintervention or Amputation Following Endovascular Infrainguinal Lower Extremity Revascularization for Non-limb threatening ischemia:** Percentage of patients undergoing endovascular infrainguinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) who do not require ipsilateral repeat revascularization or any amputation within one year The measure steward withdrew support of this measure as the measure specifications are incomplete at this time. For this reason, CMS is not finalizing this measure for PQRS 2015 but may consider this measure for a future program year.	SVS			X				
N/A /N/A	N/A	Effective Clinical Care	**Freedom from Reintervention or Amputation Following Open Infrainguinal Lower Extremity Revascularization for non-limb threatening ischemia:** Percentage of patients undergoing open infrainguinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) who do not require ipsilateral repeat revascularization or any amputation within one year The measure steward withdrew support of this measure as the measure specifications are incomplete at this time. For this reason, CMS is not finalizing this measure for PQRS 2015 but may consider this measure for a future program year.	SVS			X				
662 /N/A	N/A	Communication and Care Coordination	**Median Time to Pain Management for Long Bone Fracture:** Median time from emergency department (ED) arrival to time of initial oral, intranasal or parenteral pain medication administration for emergency department patients with a principal diagnosis of long bone fracture (LBF) While some commenters supported the inclusion of this measure in PQRS, after further review CMS determined that comparison across measurement periods, particularly when the reporting period for the PQRS payment adjustments is a 12-month calendar year, poses an analytic challenge for reporting purposes. CMS currently does not have a measure in the PQRS where data is collected outside a respective reporting period and compared to an existing reporting period without an	CMS/OFMQ			X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			established performance met target. While we welcome intermediate outcome measures such as these, it is not technically feasible at this time to include this measure in the PQRS. For this reason, CMS is not finalizing its proposal to make this measure reportable beginning in 2015 for PQRS.								

¥ 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 54, we provide our responses and final decisions on the measures for which we proposed a NQS domain change for reporting under the PQRS (79 FR 40419). Please note that we received comments regarding the process for changing a measure's domain. With respect to these comments, we appreciate the commenters' suggestions regarding the process for domain changes for measures and will take these comments under consideration. We are developing guidelines for assigning measure domains and will use these guidelines to assign each measure in the PQRS program to a NQS domain when measure stewards submit measures through the Call for Measures process each program year. We value feedback from measure developers and are dedicated to making updates to the PQRS program a transparent and collaborative process as it works to establish measures that are applicable to various domain categories.

TABLE 54: NQS Domain Changes for Individual Quality Measures and Those Included in Measures Groups for the PQRS Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed											
0097/046	N/A	Patient Safety	Communication and Care Coordination	**Medication Reconciliation:** Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented. This measure is reported as two rates stratified by age group: Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older. Commenters supported the proposed domain change for PQRS #46 from Patient Safety to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.	X		X				
0650/137	N/A	Effective Clinical Care	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment Commenters supported the proposed domain change for PQRS #137 from Effective Clinical Care to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/288	N/A	Effective Clinical Care	Communication and Care Coordination	**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 Commenters disagreed with the proposed domain change but did not explain why. However, while this measure does fall into both the Communication and Care Coordination and Person and Caregiver-Centered						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				Experience and Outcomes domains, Communication and Care Coordination should become the new primary domain. While the measure does target the education and referral of the patient's caregiver to supportive services, this is a secondary goal of the measure -- the primary intent is to disseminate information related to caring for a patient with dementia, including making connections to all potentially necessary providers. For these reasons, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/A/293	N/A	Effective Clinical Care	Communication and Care Coordination	**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 (for example, physical, occupational, or speech therapy) discussed at least annually No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	
N/A/294	N/A	Effective Clinical Care	Communication and Care Coordination	**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 (for example, non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	
N/A/325	N/A	Effective Clinical Care	Communication and Care Coordination	**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 another clinician with communication to the clinician treating the comorbid condition Commenters supported the proposed domain change for PQRS #325 from Effective Clinical Care to Communication and Care Coordination. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/303	N/A	Effective Clinical Care	Person and Caregiver-	**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			X			X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			Centered Experience and Outcomes	improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/A/331	N/A	Effective Clinical Care	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis or within 10 days after onset of symptoms Commenters supported the proposed domain change for PQRS #331 from Effective Clinical Care to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X			X	
N/A/332	N/A	Effective Clinical Care	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin 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 clavulante, as a first line antibiotic at the time of diagnosis Commenters supported the proposed domain change for PQRS #332 from Effective Clinical Care to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X			X	
N/A/347	N/A	Effective Clinical Care	Patient Safety	**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 No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/348	N/A	Effective Clinical Care	Patient Safety	**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 No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/354	N/A	Effective Clinical Care	Patient Safety	**Anastomotic Leak Intervention:** Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				or colectomy surgery No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/A/355	N/A	Effective Clinical Care	Patient Safety	**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 No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	
0043/111	127v3	Effective Clinical Care	Community/Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.	X		X	X	X	X	ACO MU2
0321/082	N/A	Communication and Care Coordination	Effective Clinical Care	**Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months Commenters supported the proposed domain change for PQRS #82 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/180	N/A	Communication and Care Coordination	Effective Clinical Care	**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 Commenters supported the proposed domain change for PQRS #180 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.						X	AQA
N/A/280	N/A	Communication and Care Coordination	Effective Clinical Care	**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 Commenters supported the proposed domain change						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				for PQRS #280 from Communication and Care Coordination to Effective Clinical Care. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
0654/093	N/A	Communication and Care Coordination	Efficiency and Cost Reduction	**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 Commenters supported the proposed domain change for PQRS #93 from Communication and Care Coordination to Efficiency and Cost Reduction. For this reason, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.	X		X			X	
N/A/258	N/A	Communication and Care Coordination	Patient Safety	**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) No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/259	N/A	Communication and Care Coordination	Patient Safety	**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) No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
N/A/260	N/A	Communication and Care Coordination	Patient Safety	**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 No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.			X				
1525/326	N/A	Patient Safety	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular	X		X				

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				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 One commenter agreed while another commenter disagreed with the proposal to change the domain of PQRS #326 from Patient Safety to Effective Clinical Care noting "providing anticoagulation therapy for atrial fibrillation and atrial flutter patients is a means of reducing the risk of stroke in patients presenting for more high- or moderate-risk factors." While not using warfarin or another anticoagulation therapy is "a means of reducing the risk of stroke in patients presenting for more high- or moderate-risk factors," this is a secondary outcome of providing the medication, not a direct risk caused by the delivery of care. So, while taking warfarin or another anticoagulant may provide protection against stroke, it is not the primary intent of the measure. For these reasons, CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.							
N/A/321	N/A	Communication and Care Coordination	Person and Caregiver Experience and Outcomes	**CAHPS for PQRS Clinician/Group Survey:** • 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 No comments were received regarding the domain for this measure. CMS is finalizing its proposal to change the domain of this measure for 2015 PQRS.		X					ACO
Measures Not Finalized as Proposed											
N/A/356	N/A	Effective Clinical Care	Communication and Care Coordination	**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 One commenter disagreed with CMS' proposal to change the domain of this measure noting that "unplanned readmissions can be the result of many factors which extend well beyond communication and care coordination." The commenter suggested keeping						X	

NQF/ PQRS	CMS E-Measure ID	NQS Domain 2014	NQS Domain 2015	Measure Title and Description	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
				Effective Clinical Care as the NQS domain. CMS agreed with the commenter and is not finalizing its proposal to change the domain of PQRS #356 from Effective Clinical Care to Communication and Care Coordination for 2015 PQRS. This measure will remain as Effective Clinical Care in the 2015 PQRS measure set.							

¥ 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 55, we provide the responses and final decisions related to the measures we proposed to remove from reporting under the PQRS (79 FR 40426).

TABLE 55: Measures Being Removed from the Existing PQRS Measure Set Beginning in 2015

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed										
0270/020	Patient Safety	**Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, 2 hours), prior to the surgical incision (or start of procedure when no incision is required) Some commenters disagreed with CMS' proposal to remove this measure noting "disparate practice patterns among clinicians when selecting the more appropriate prophylactic antibiotic." However, other commenters agreed with CMS' proposal to remove this measure given the measure's "emphasis on administration rather than ordering of antibiotics." For this reason and given the measure's high rate of performance in previous reporting years, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI NCQA	X		X			X	
0092/028	Effective Clinical Care	**Aspirin at Arrival for Acute Myocardial Infarction (AMI):** Percentage of patients, regardless of age, with an emergency department discharge diagnosis of acute myocardial infarction (AMI) who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay Commenters disagreed with CMS' proposal to remove this measure noting it presents a "reporting opportunity for emergency physicians" which could create a reporting gap for that segment of providers reporting to PQRS. However, CMS continues to believe this measure represents a clinical concept that has been substantially adopted for initial treatment of patients suffering from acute myocardial infarction when clinically indicated. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI NCQA	X		X				
0269/030	Patient Safety	**Perioperative Care: Timing of Prophylactic Antibiotic—Administering Physician:** Percentage of surgical patients aged 18 years and older who receive an anesthetic when undergoing procedures with the indications for prophylactic	AAO	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		parenteral antibiotics for whom administration of a prophylactic parenteral antibiotic ordered has been initiated within 1 hour (if fluoroquinolone or vancomycin, 2 hours) prior to the surgical incision (or start of procedure when no incision is required) Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represents a clinical performance gap that should be measured by the PQRS Program. Additionally, CMS will apply the Measure Applicability Validation (MAV) process for claims-based reporting in those cases where specialists do not have enough relevant measures to report. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0240/031	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Venous Thromboembolism (VTE) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who were administered venous thromboembolism (VTE) prophylaxis the day of or the day after hospital admission Commenters disagreed with CMS' proposal to remove this measure. Commenters maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS believes this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AANI	X		X				
0243/035	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Screening for Dysphagia:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the institution in which the patient is receiving care	AANI	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Commenters disagreed with CMS' proposal to remove this measure as they maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS continues to believe this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0244/036	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge Commenters disagreed with CMS' proposal to remove this measure as they maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS continues to believe this measure represents a basic standard of care and does not add clinical value to PQRS at this time. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AANI	X		X				
0637/045	Patient Safety	**Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Cardiac Procedures):** Percentage of 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 48 hours of surgical end time Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached	AMA-PCPI NCQA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0099/049	Effective Clinical Care	**Urinary Incontinence: Characterization of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence whose urinary incontinence was characterized at least once within 12 months Commenters disagreed with removal of this measure due to high performance rates indicating this is not a good enough reason to remove a measure from the program. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.	NCQA/ AMA-PCPI	X		X				
0093 /055	Effective Clinical Care	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope:** Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who had a 12-lead electrocardiogram (ECG) performed Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI /NCQA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0232 /056	Effective Clinical Care	**Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Vital Signs:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with vital signs documented and reviewed Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI /NCQA	X		X				
0096 /059	Effective Clinical Care	**Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Empiric Antibiotic:** Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with an appropriate empiric antibiotic prescribed Commenters disagreed with CMS' proposal to remove this measure noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI /NCQA	X		X				
0001/064	Effective Clinical Care	**Asthma: Assessment of Asthma Control – Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least once during the measurement period for asthma control (comprising asthma impairment and asthma risk)	AMA-PCPI NCQA			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Some commenters disagreed with the removal of this measure noting "this [assessment] is essential in order to ensure appropriate treatment for asthma which currently is less than optimal." However, other commenters supported the removal of this measure. CMS continues to believe this measure represents a basic clinical concept that does not add clinical value to PQRS because in order to provide effective treatment for asthma, assessment of asthma control is essential. As such, CMS is finalizing its proposal to remove PQRS #064, "Asthma: Assessment of Asthma Control – Ambulatory Care Setting," which is a process measure, and replace it with the more robust outcome measure, Optimal Asthma - Control Component based on our exception authority under section 1848(k)(2)(C)(ii) of the Act that provides an exception to the requirement that the Secretary select measures must be endorsed by NQF.									
0393/083	Effective Clinical Care	**Hepatitis C: Confirmation of Hepatitis C Viremia:** Percentage of patients aged 18 years and older who are hepatitis C antibody positive seen for an initial evaluation for whom hepatitis C virus (HCV) RNA testing was ordered or previously performed One commenter disagreed with the removal of this measure noting a recent study of four large health systems revealed that "less than two-thirds of persons with positive HCV antibody test had a follow-up RNA test." Despite these findings, eligible professionals have consistently reported performance rates close to 100% for this measure. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represents a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AGA			X				
0103/106	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity:** Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of major depressive disorder	APA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		(MDD) with evidence that they met the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria for MDD AND for whom there is an assessment of depression severity during the visit in which a new diagnosis or recurrent episode was identified Commenters disagreed with CMS' proposal to remove this measure noting "appropriate diagnosis and classification of severity are essential in order to ensure appropriate treatment for major depressive disorder. The use of the diagnostic tools included in the measure is currently less than optimal." Furthermore, commenters suggest the other MDD measure (PQRS #370) "does not include screening for bipolar disorder and could potentially exclude some patients from screening." However, CMS continues to believe it represents a clinically diagnostic reference that is commonly utilized as a standard practice of care in order to diagnose and treat mental health disorders. This measure is not robust and does not add clinical value to the PQRS program. It is a goal of CMS to increase the number of outcome-based measures in the PQRS program, and measures that work to appropriately diagnose and classify the severity of illnesses and include quality care action are essential for this effort. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
1666/123	Effective Clinical Care	**Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL:** Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy ([RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy AND have a hemoglobin level > 12.0 g/dL Some commenters suggested CMS not remove this measure, noting it is "an assessment that is required for making treatment decisions." CMS agrees this measure is both an effective clinical care and overuse measure. However,	RPA	X		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		commenters that agreed with removal of this measure came from specialists who would most likely be reporting this measure. As such, CMS is finalizing its proposal to remove PQRS 123.								
0051/142	Effective Clinical Care	**Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with an assessment for use of anti-inflammatory or analgesic over-the-counter (OTC) medications A steward has still not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI	X		X				
0322/148	Efficiency and Cost Reduction	**Back Pain: Initial Visit:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain Some commenters supported the removal of this measure while others expressed concern over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PQRS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care, and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.	NCQA						X	
0319/149	Effective Clinical Care	**Back Pain: Physical Exam:** Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain Some commenters supported the removal of this measure while others expressed concern	NCQA						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PRQS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.								
0314/150	Effective Clinical Care	**Back Pain: Advice for Normal Activities**: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain Some commenters expressed concern over the removal of this measure and the negative impact on anesthesiologists and pain medicine physicians to report PRQS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.	NCQA						X	
0313/151	Effective Clinical Care	**Back Pain: Advice Against Bed Rest:** The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain	NCQA						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Some commenters supported the removal of this measure while others expressed concern over its removal and the negative impact on anesthesiologists and pain medicine physicians to report PRQS. CMS understands the commenters' concerns. It is a priority for PQRS to ultimately increase the quality of health care and promoting outcome-based measures is part of this effort. This measure and others in the Back Pain Measure Group represent clinical assessments and recommendations commonly utilized to provide effective treatment for patients diagnosed with back pain, and thus, were determined to be low bar, process-based measures that do not meaningfully contribute to improved patient outcomes or the PQRS program. For this reason, CMS is finalizing its proposal to remove this measure and other measures in the Back Pain Measures Group from the PQRS program in 2015.								
0455/157	Patient Safety	**Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal Cancer Resection:** Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.	STS	X		X				
0404/159	Effective Clinical Care	**HIV/AIDS: CD4+ Cell Count or CD4+ Percentage Performed:** Percentage of patients aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or CD4+ cell percentage was performed at least once every 6 months Commenters disagreed with the removal of this measure based on a rationale of a high performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer	AMA-PCPI NCQA			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. Furthermore, other commenters agreed with the removal of this measure indicating "this measure is no longer as relevant now that we are measuring CD4 less frequently and such measurement is optional in the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents for those suppressed for at least 2 years." For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0116/169	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.	STS			X			X	
0117/170	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-blockers Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical	STS			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.								
0118/171	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge**: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on a statin or other lipid-lowering regimen Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.	STS			X			X	
0074/197	Effective Clinical Care	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin Many commenters supported the proposed removal of the measure because the measure may not align with current clinical guidelines. Other commenters disagreed with the removal of this measure indicating the measure is currently in the process of being updated. CMS continues to believe that because of changes to the applicable evidence-based guidelines, this measure is no longer clinically valid. For this reason, CMS is finalizing its proposal to remove this measure from reporting for 2015 PQRS and Medicare Shared Savings Program.	AMA-PCPI ACCF AHA			X		X	X	
0079/198	Effective Clinical Care	**Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment:** Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period	AMA-PCPI ACCF AHA			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Several comments suggested CMS maintain this measure as it is important to clinical practice and has strong impact on patient symptom management. However, CMS continues to believe this measure represents a clinical concept that does not add clinical value to PQRS. LVEF testing is basic assessment for patients with heart failure. For these reasons, CMS is finalizing its proposal to remove this measure from 2015 PQRS.								
N/A /228	Effective Clinical Care	**Heart Failure (HF): Left Ventricular Function (LVF) Testing:** Percentage of patients 18 years and older with Left Ventricular Function (LVF) testing documented as being performed within the previous 12 months or LVF testing performed prior to discharge for patients who are hospitalized with a principal diagnosis of Heart Failure (HF) during the reporting period Several comments suggested CMS maintain this measure as it is important to clinical practice. However, CMS continues to believe this measure represents a clinical concept that does not add clinical value to PQRS. LVF testing is basic assessment for patients with heart failure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	CMS/QIP			X				
N/A/231	Effective Clinical Care	**Asthma: Tobacco Use: Screening - Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period Commenters disagreed with CMS' proposal to replace PQRS #231 (Asthma: Tobacco Use: Screening - Ambulatory Care Setting) with PQRS #226 "Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention" because PQRS #231 includes an age range of 5-64 while the lower bound age for PQRS #226 is 18 years, missing the pediatric population. Furthermore, PQRS #226 does not include the query regarding exposure to second hand smoke which is critical for the 18 and under population with Asthma. However, CMS continues to believe this is measure is appropriate and more broadly applicable and for this reason is finalizing the proposal	AMA-PCPI NCQA	X		X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		to remove this measure from 2015 PQRS reporting.								
N/A/232	Effective Clinical Care	**Asthma: Tobacco Use: Intervention - Ambulatory Care Setting**: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were identified as tobacco users (or their primary caregiver) who received tobacco cessation intervention at least once during the one-year measurement period Commenters disagreed with CMS' proposal to replace PQRS #232 (Asthma: Tobacco Use: Intervention - Ambulatory Care Setting) with PQRS #226 "Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention" because PQRS #231 and #232 include an age range of 5-64 while the lower bound age for PQRS #226 is 18 years, missing the pediatric population. Furthermore, PQRS #226 does not include the query regarding exposure to second hand smoke which is critical for the 18 and under population with Asthma. However, CMS continues to believe #226 is appropriate and more broadly applicable and for this reason is finalizing its proposal to remove #232 from 2015 PQRS reporting.	AMA-PCPI NCQA	X		X			X	
0457/233	Effective Clinical Care	**Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection:** Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer for whom performance status was documented and reviewed within 2 weeks prior to surgery Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.	STS			X				
0458/234	Patient Safety	**Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy):** Percentage of thoracic surgical patients aged 18 years and	STS			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy) Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from 2015 PQRS.								
AQA Adopted /245	Effective Clinical Care	**Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers (Overuse Measure):** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without the use of a wound surface culture technique Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. However, other commenters supported the removal of this measure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ASPS	X		X				
AQA Adopted /246	Effective Clinical Care	**Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers (Overuse Measure):** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without a prescription or recommendation to use wet to dry dressings Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer	ASPS	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. However, other commenters supported the removal of this measure. For these reasons, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
AQA Adopted/ 247	Effective Clinical Care	**Substance Use Disorders: Counseling Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12-month reporting period Commenters disagreed with removal of this measure based on a rationale of high performance rates. With a performance rate above 90 percent for multiple consecutive years, CMS considers the measure to have reached its potential, and no longer represent a clinical performance gap that should be measured by the PQRS Program. The PQRS will continue to focus on measures with maximal potential for improvement and that answer a clinical performance gap. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	APA	X		X				AQA
AQA Adopted/ 248	Effective Clinical Care	**Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence:** Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period One commenter reported this measure is not applicable to nursing home providers. No other comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	APA	X		X				AQA
N/A /266	Effective Clinical Care	**Epilepsy: Seizure Type(s) and Current Seizure Frequency(ies):** Percentage of patient visits with a diagnosis of epilepsy who had the type(s) of seizure(s) and current seizure frequency(ies) for each seizure type documented in the medical	AAN	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		record No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/ 267	Effective Clinical Care	**Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome:** All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AAN	X		X				
N/A/ 269	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented**: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period One commenter disagreed with the removal of this measure but did not provide a reason. However, CMS continues to believe that, as a measurement tool, PQRS #269 did not add clinical value to the PQRS Program because in order to provide care for IBD patients, documentation of type, anatomic location and activity would be essential for effective treatment of the disease. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AGA						X	
N/A/ 272	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year Commenters were supportive of the removal of this measure and its replacement with PQRS #110 (Preventive Care and Screening: Influenza Immunization) if language were added to the replacement measure to include IBD. CMS continues to believe this measure is duplicative of PQRS #110, which is also more broadly applicable. For this reason, CMS is	AGA						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		finalizing its proposal to remove this measure from reporting in 2015 PQRS and will work with the measure steward to address the question of expanding the age range of PQRS #110.								
N/A/ 273	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received Commenters were supportive of the removal of this measure and its replacement with PQRS #111 (Pneumonia Vaccination Status for Older Adults) if language were added to the replacement measure to include IBD patients and address age range differences between the two measures as PQRS #111 does not address the under 65 population. CMS has confirmed with the measure steward for PQRS #111 that the age range can be adjusted. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AGA						X	
N/A/295	Effective Clinical Care	**Hypertension: Use of Aspirin or Other Antithrombotic Therapy:** Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/ 296	Effective Clinical Care	**Hypertension: Complete Lipid Profile:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 60 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/297	Effective Clinical Care	**Hypertension: Urine Protein Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months. Commenters disagreed with the removal of	ABIM						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		this measure noting that without it, there will "no longer be a quality measure in PQRS that assesses kidney function for people at high risk of chronic kidney disease." Unfortunately, these measures cannot remain in the PQRS program without a measure steward. Given a steward has not been identified for this measure CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/298	Effective Clinical Care	**Hypertension: Annual Serum Creatinine Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/299	Effective Clinical Care	**Hypertension: Diabetes Mellitus Screening Test:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/300	Effective Clinical Care	**Hypertension: Blood Pressure Control:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent blood pressure was under control (< 140/90 mmHg) A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
N/A/ 301	Effective Clinical Care	**Hypertension: Low Density Lipoprotein (LDL-C) Control**: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had most recent LDL cholesterol level under control (at goal) Commenters disagreed with the proposal to remove this measure "until new measures that are more consistent with new and existing guidelines are put in place to replace it." However, this measure is no longer in accordance with new evidence-based clinical guidelines regarding lipid control. CMS understands the commenters' concerns that removing measures may lead	ABIM						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		to program gaps; however, it is a priority for PQRS to ultimately increase the quality of health care and this goal was at the forefront of consideration for the removal of these measures. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/302	Effective Clinical Care	**Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed:** Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months A steward has not been identified for this measure, and for this reason CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	ABIM						X	
2080/341	Efficiency and Cost Reduction	**Gap in HIV Medical Visits:** Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months No comments were received regarding this measure. CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS.	HRSA			X			X	
Measures Not Finalized as Proposed										
0087/014	Effective Clinical Care	**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 Commenters disagreed with removal of this measure, noting that removal based on a "high-performance rate when EP reporting within the PQRS program is low" may not be appropriate. We have also received strong comments and feedback from outside stakeholders that this measure is still relevant to its eligible professionals. Some commenters note that the "high performance rate" may be skewed and not accurately reflect the existing gap addressed by this measure. CMS agrees with commenters and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS continues to look for better	AAO	X		X					

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		outcome measures, and as such this measure may be considered for removal in a future program year.								
0268/021	Patient Safety	**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 Commenters disagreed with CMS' proposal to remove this measure, noting "it is premature to remove a measure based on a high-performance rate when the EP reporting rate within the PQRS program is low." CMS agrees with commenters that removing this measure may negatively impact providers' ability to report to PQRS and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its proposal to remove the Perioperative Care Measure Group, and for this reason this measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	AMA-PCPI NCQA	X		X				
0271/022	Patient Safety	**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 Some commenters disagreed with CMS' proposal to remove this measure, noting "disparate practice patterns among clinicians when selecting the more appropriate prophylactic antibiotic." Furthermore, commenters note it might be premature to remove a measure based on a high-performance rate. CMS agrees with commenters and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its proposal to remove the Perioperative Care Measure Group, and for this reason this	AMA-PCPI NCQA	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.								
0239/023	Patient Safety	**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 Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. CMS agrees with commenters that removing this measure may negatively impact providers' ability to report to PQRS and therefore is not finalizing its proposal to remove this measure from 2015 PQRS. However, CMS is finalizing its proposal to remove the Perioperative Care Measure Group, and for this reason this measure will only be reportable through claims and registry for 2015 PQRS. CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	AMA-PCPI NCQA	X		X				
0325/032	Effective Clinical Care	**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) who were prescribed antithrombotic therapy at discharge Some commenters agreed while others disagreed with CMS' proposal to remove this measure due to this measure representing a clinical concept that is currently included within inpatient standard of care to decrease risk of complications in patients diagnosed with ischemic or intracranial stroke when clinically indicated. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as	AANI	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		such this measure may be considered for removal in a future program year.								
0241/033	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge Commenters disagreed with CMS' proposal to remove this measures based on the rationale that they represent clinical concepts that are currently included within inpatient standards of care to improve patient outcomes for those diagnosed with ischemic or intracranial stroke when clinically indicated. Commenters maintain that these clinical concepts are appropriate for measurement at the individual physician level in addition to the facility level to help ensure the continuous care of stroke patients. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	AANI			X				
0091/051	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	American Thoracic Society			X			X	
0102/052	Effective Clinical Care	**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 FEV_1/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	American Thoracic Society			X			X	
0050/109	Person and Caregiver-	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for	AAOS			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
	Centered Experience and Outcomes	patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0566/140	Effective Clinical Care	**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 Commenters disagreed with removal of this measure noting that removal based on a "high-performance rate when EP reporting within the PQRS program is low" may not be appropriate. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	AAO	X		X				
0508/146	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign" Commenters disagreed with the removal of this measure based on a rationale of a high performance rate. Furthermore one commenter notes "this measure is important in that it ensures the integrity of the complete mammography audit." CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	AC Radiology / AMA-PCPI	X		X				
N/A/147	Communication and Care Coordination	**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	SNMMI	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		documentation of correlation with existing relevant imaging studies (for example, x-ray, MRI, CT, etc.) that were performed. A steward has been identified for this measure, and as a result CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
0115/168	Effective Clinical Care	**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 Commenters disagreed with removal of this measure noting that removal based on a high-performance rate. CMS agrees with commenters that this may negatively impact the ability of certain specialties to report PQRS, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	STS			X			X	
AQA Adopted/ 173	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months A measure steward has been identified for this measure, and as such CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI			X			X	
0643/243	Effective Clinical Care	**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	ACCF AHA			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		Commenters disagreed with CMS' proposal to remove this measure, suggesting that "while the clinical condition may initiate in the inpatient setting, the clinical process being measured is limited to the outpatient setting and would therefore add clinical value to outpatient care of the cardiac rehabilitation patient." Further, commenters note that there is "clear evidence that processes to improve referral of eligible patients to cardiac rehabilitation result in improved cardiac rehabilitation participation rates and improved patient outcomes." CMS agrees with the commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.								
N/A/ 257	Effective Clinical Care	**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 Commenters disagreed with the proposed removal of this measure on the basis that the measure represents a current standard of care. CMS agrees with commenters, and for this reason CMS is not finalizing its proposal to remove this measure from reporting for 2015 PQRS. However, CMS continues to look for better outcome measures, and as such this measure may be considered for removal in a future program year.	SVS			X				
N/A/ 261	Communication and Care Coordination	**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 Commenters disagreed with CMS' proposal to remove this measure with the rationale that it represents a clinical concept that is common practice in order to provide effective treatment for patients. Commenters request reconsideration for CY 2015 to ensure audiologists have enough clinically-relevant measures to report. For this reason, CMS is not finalizing its proposal to remove this measure from	AQC	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		reporting in 2015 PQRS.								
N/A/276	Effective Clinical Care	**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 A steward has been identified for this measure and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AASM/ AMA-PCPI						X	
N/A/277	Effective Clinical Care	**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 A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AASM/ AMA-PCPI						X	
N/A/278	Effective Clinical Care	**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 A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AASM/ AMA-PCPI						X	
N/A/279	Effective Clinical Care	**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 A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AASM/ AMA-PCPI						X	
N/A/335	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and <	AMA-PCPI			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
		39 weeks of gestation completed who had elective deliveries or early inductions without medical indication A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.								
N/A/336	Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning A steward has been identified for this measure, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2015 PQRS.	AMA-PCPI			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 56, we provide our responses and final decisions related to our proposals to change the way in which previously established measures in the PQRS will be reported beginning in 2015 (79 FR 40441).

TABLE 56: Existing Individual Quality Measures and Those Included in Measures Groups for the PQRS for Which Measure Reporting Updates Will Be Effective Beginning in 2015

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
Measures Finalized as Proposed											
006 4/0 02	163 v3	Effective Clinical Care	**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 Commenters expressed concern with maintaining this measure in PQRS for EHR reporting only for the "sake of alignment with the EHR Incentive Program especially in the face of changing [clinical] evidence." However, due to our desire to align with the EHR Incentive Program, CMS will not make changes to EHR measures until the EHR Incentive Program is able to change this measure. CMS understands commenters' concerns and will track these issues for future program years when changes are possible. CMS is finalizing its proposal to make this measure reportable in 2015 PQRS through EHR only.	NCQA				X			MU2 Million Hearts
006 7/0 06		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. CMS also received comments supporting inclusion of the measure in the Shared Savings Program CAD Composite measure but with composite measure testing and NQF review. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden. CMS will not finalize adding this measure in the Shared Savings Program CAD Composite.	AMA-PCPI ACCF AHA			X		X	X	ACO
010 5/0	128 v3	Effective Clinical	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and	NCQA				X			MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
09		Care	older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months). CMS is finalizing its proposal to change the reporting option of PQRS #9 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program. PQRS would otherwise propose to remove this measure from PQRS, as it is a process measure that is analytically challenging to report.								
008 8/0 18	167 v3	Effective Clinical Care	**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 One commenter disagreed with the removal of this measure. CMS initially wanted to propose removal of this measure as eligible professionals are consistently meeting performance on this measure with performance rates close to 100%. However, due to our desire to align with the EHR Incentive Program, under which this measure is also available for reporting in 2015, CMS proposed to maintain this measure in PQRS for EHR reporting only, removing all other reporting options, until the EHR Incentive Program can change this measure. CMS is finalizing removal of this measure from reporting for 2015 PQRS for all other reporting options.	AMA-PCPI NCQA				X			MU2
013 4/0 43		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the	STS			X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.								
0377/067		Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: 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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.	AMA-PCPI ASH			X				
0378/068		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant	AMA-PCPI ASH			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.								
0380/069		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	AMA-PCPI ASH			X				
0379/070		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	AMA-PCPI ASH			X				
0395/084		Effective Clinical Care	**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) RNA	AGA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			testing was performed within 12 months prior to initiation of antiviral treatment While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures.								
0396/085		Effective Clinical Care	**Hepatitis C: 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 While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AGA						X	
0398/087		Effective Clinical Care	**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	AGA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4-12 weeks after the initiation of antiviral treatment While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
0389/102	129 v3	Efficiency and Cost Reduction	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	AMA-PCPI			X	X			MU2
0390/104		Effective Clinical Care	**Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients:** 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	AMA-PCPI			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			hormone] agonist or antagonist) Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.								
0104/107	161 v3	Effective Clinical Care	**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 CMS is finalizing its proposal to change the reporting option of PQRS #107 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program when PQRS would otherwise propose to remove this measure from PQRS, as it is a process measure that is analytically challenging to report. PQRS will keep this measure as EHR-reportable until the EHR Incentive Program is able to change this measure.	AMA-PCPI				X			MU2
0054/108		Effective Clinical Care	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD) While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual	NCQA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
1668/121		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	RPA			X			X	
AQA Adopted/122		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	RPA			X			X	AQA
0405/160	52v3	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	NCQA						X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
AQA Adopted/ 176		Effective Clinical Care	**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) While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AC Rheumatology						X	AQA
AQA Adopted/ 177		Effective Clinical Care	**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 While several comments were concerned	AC Rheumatology						X	AQA

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
AQA Adopted/ 179		Effective Clinical Care	**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 While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AC Rheumatology						X	AQA
AQA Adopted /180		Effective Clinical Care	**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 While several comments were concerned	AC Rheumatology						X	AQA

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
0399/183		Community / Population Health	**Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV):** 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 While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	AGA						X	
0386/194		Effective Clinical Care	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period Several commenters were concerned with CMS' proposal to eliminate the claims-based	AMA-PCPI ASCO			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden. Note that this measure is no longer part of a measures group as well.								
0022/238	156 v3	Patient Safety	**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 No comments were received regarding this measure. CMS is finalizing its proposal to add registry as a reporting option for this measure in 2015 PQRS.	NCQA			X	X			MU2
0075/241	182 v4	Effective Clinical Care	**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) CMS is finalizing its proposal to change the reporting option of PQRS #241 to EHR-only reporting as part of its efforts to align with the EHR Incentive Program when PQRS would otherwise propose to remove this measure from PQRS 2015. PQRS will keep this measure as EHR reportable until the EHR Incentive Program can change this measure.	NCQA				X			MU2 Million Hearts
N/A/32		Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period	RPA			X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
7			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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS as part of its goal to lower the data error rate and decrease provider burden.								
1667/328		Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that not all eligible professionals have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns and believes that removal of the claims-based reporting option will not negatively impact a significant number of providers reporting these measures. Therefore, CMS is finalizing its proposal to remove the claims-based reporting option for this measure in 2015.	RPA			X				
2082/338		Effective Clinical Care	**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 viral load test during the measurement year While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen	HRSA						X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures								
2083/339		Effective Clinical Care	**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 While several comments were concerned with the removal of reporting options for some measures, CMS is finalizing its proposal to make this individual measure reportable via measures groups-only to lessen the burden of eligible professionals reporting individual measures based on the current requirement of nine measures over three domains. While removing reporting options could be seen as increasing burden for eligible professionals, as they have fewer choices to report this measure, we do not believe this is the case with reporting via measures groups. For example, an individual eligible professional reporting via a measures group only need to report on a minimum of 6 measures rather than a minimum of 9 measures covering 3 NQS domains, as is the case with reporting individual measures	HRSA						X	
2079/340		Efficiency and Cost Reduction	**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 This measure was included on this table in error in the proposed rule. There are no changes proposed for this measure in 2015 PQRS. This measure was reportable through measure groups only in PQRS 2014 and will continue to be similarly reportable in PQRS 2015.	HRSA						X	
0710/370	159 v3	Effective Clinical Care	**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	MNCM				X	X		MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			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 CMS did not receive any comments regarding the proposal to add registry as a reporting option for this measure. As such, CMS is finalizing this proposal for 2015 PQRS.								
Measures Not Finalized as Proposed											
0086/012	143 v3	Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA-PCPI NCQA	X		X	X			MU2
0089/019	142 v3	Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to	AMA-PCPI NCQA	X		X	X			MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0045/024		Communication and Care Coordination	**Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, this measure is a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA-PCPI NCQA	X		X				
0046/039		Effective Clinical Care	**Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the	AMA-PCPI NCQA	X		X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this measure as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0048/040		Effective Clinical Care	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients **aged 50 years and older** with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA-PCPI NCQA	X		X				
0097/046		Communication and Care Coordination	**Medication Reconciliation:** Percentage of patients aged 18 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented. This measure is reported as two rates stratified by age group: Reporting Age Criteria 1: 18-64 years of age Reporting Age Criteria 2: 65 years and older	AMA-PCPI NCQA	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0100/050		Person and Caregiver-Centered Experience and Outcomes	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, CMS identified this measure as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	NCQA AMA-PCPI	X		X				
0090/054		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting	AMA-PCPI NCQA	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0387/071	140 v3	Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA-PCPI ASCO NCCN	X		X	X		X	MU2
0385/072	141 v3	Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the	AMA-PCPI ASCO NCCN	X		X	X		X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
N/A/112		Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	NCQA	X		X	X	X	X	MU2
0034/113	130v3	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS identified this as a broadly applicable, preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	NCQA	X		X	X	X	X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
0055/117	131 v3	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. In addition, many commenters supported the inclusion of the measure within the Shared Savings Program Diabetes Composite, but requested testing of the Composite measure and submission to NQF. Some commenters did not support the addition of a process measure to the Shared Savings Program measure set and questioned the measure's link to improving outcomes. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years. CMS will finalize adding the measure to the Shared Savings Program Diabetes Composite due to its clinical importance, alignment with PQRS, and stakeholder support.	NCQA	X		X	X	X	X	ACO MU2
0062/119	134 v3	Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the	NCQA	X		X	X		X	MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			claims-based option. Furthermore, CMS identified this measure as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0563/141		Communication and Care Coordination	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AAO	X		X				
0056/163	123v3	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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Furthermore, CMS	NCQA	X		X	X		X	ACO MU2

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			identified this as a preventive care measure. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0659/185		Communication and Care Coordination	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AGA ASGE ACG	X		X				
0068/204	164 v3	Effective Clinical Care	**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 Commenters expressed concern with maintaining this measure in PQRS for EHR reporting only for the "sake of alignment with the EHR Incentive Program especially in the face of changing [clinical] evidence." However, due to CMS's desire to maintain	NCQA	X		X	X	X		MU2 Million Hearts

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			alignment with the EHR Incentive Program, CMS will not make changes to EHR measures until the EHR Incentive Program is able to change this measure. commentsfrombut CMS is not finalizing its proposal to remove the claims, registry and GPRO reporting options for this measure. This measure will continue to be reportable through claims, registry, GPRO (including the Shared Savings Program), as well as EHR in PQRS 2015. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0409/205		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	NCQA AMA-PCPI	X					X	
0651/254		Effective Clinical Care	**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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the	ACEP	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
0652/255		Effective Clinical Care	**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) Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	ACEP	X		X				
N/A/268		Effective Clinical Care	**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 about epilepsy and how its treatment may affect contraception and pregnancy at least once a year Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be	AAN	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
N/A/270		Effective Clinical Care	**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 600mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy in the last reporting year Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.	AGA			X			X	
N/A/271		Effective Clinical Care	**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 Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.	AGA			X			X	
N/A/274		Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of	AGA			X			X	

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			patients aged 18 years and older with a diagnosis of inflammatory bowel disease 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 Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.								
N/A/275		Effective Clinical Care	**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 Commenters requested this IBD measure and others noted in this table be reportable through registry in addition to the IBD Measure Group to better support providers reporting these measures. CMS agrees, and for this reason CMS is finalizing this measure with modifications as reportable in 2015 PQRS through registry and measure group.	AGA			X			X	
0658/320		Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 years and older 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 Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not	AGA ASGE ACG	X		X				

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups	Other Quality Reporting Programs
			finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.								
1525/326		Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 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 $CHADS_2$ risk stratification, who were prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for various measures, noting that eligible professionals who may have reported on these measures do not have the resources to implement registry or EHR reporting and will no longer be able to participate in PQRS. Upon further review, CMS agrees that a significant number of providers that report this measure will be negatively impacted by the removal of the claims-based option. Therefore, CMS is not finalizing its proposal to remove the claims-based reporting option for this measure in 2015 PQRS. However, CMS is moving away from claims-based measures and therefore may reconsider the reporting options for this measure in future program years.	AMA-PCPI ACCF AHA	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 four 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.

In the CY 2014 PFS proposed rule, we proposed (78 FR 43448) to increase the number of measures that may be included in a measures group from a minimum of 4 measures to a minimum of 6. We proposed increasing the minimum number of measures that may be contained in a measures group in accordance with increasing the number of individual measures to be reported via claims and registry. However, we did not finalize this proposal, stating that, although we still plan to increase the minimum number of measures in a measures group in the future, we would work with the measure developers and owners of these measures groups appropriately to add measures to measures groups that only contain four measures within the measures group (78 FR 74730). For CY 2015, we again we proposed to modify §414.90(b) to define a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common (79 FR 40457). We solicited and received the following public comment on this proposal:

Comment: Several commenters opposed this proposal. Commenters noted that CMS did not work with the measure group developers and owners to create the proposed measures groups that consist of at least 6 measures and were concerned that the additional measures in the proposed measures groups were arbitrarily added and not relevant to the measures already contained in the measures group.

Response: While we understand the commenters' concerns that the additional measures may not be relevant to the measure group topic or condition, we note that we have performed clinical analyses to ensure that the added measures relate to the measure group topics and conditions. The addition of measures within the measures groups was not arbitrary. While some of the measures did not address the specific topic or condition depicted, we added measures within the measures groups that we believed were clinically relevant to report, as we believe these measures address topics and clinical conditions that are accepted in the clinical community as critical to monitor. For example, in most instances, we added measures from the cross-cutting measures set such as Tobacco Screening and Cessation and Medication Reconciliation. With respect to the concern that measures developers and measure owners were not consulted when developing our proposal to add measures to the measures groups, we will continue to work with the measure developers and

owners to address any concerns they may have with the final measures groups and address changes when needed through future rulemaking. Based on the reasons stated here and in the proposed rule, we are finalizing our proposal to modify §414.90(b) to define a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common.

In addition, we proposed to add two new measures groups that will be available for reporting in the PQRS beginning in 2015: the Sinusitis and Acute Otitis Externa (AOE) measures groups (79 FR 40457).

Furthermore, we proposed to remove the following measures groups (79 FR 40457):

- Perioperative care measures group;
- Back pain measures group;
- Cardiovascular prevention measures group;
- Ischemic Vascular Disease (IVD) measures group;
- Sleep Apnea measures group; and
- Chronic obstructive pulmonary disease (COPD) measures group.

We received the following comments on our proposals related to our proposals related to either the proposed addition or removal of the following measures groups:

Comments on the proposed removal of the Perioperative Care Measures Group: Several commenters requested that CMS retain the Perioperative Care Measures Group and the related individual measures noting the following: "there is a bias in measuring that improves performance; (2) there are few measures applicable to surgeons it will be much harder to participate in PQRS without the perioperative measures."

Response: While there has been evidence to suggest there may be a bias in measuring that improves performance, there is an equal amount of evidence to the contrary that suggest this

bias is not impactful. Additionally, we believe that there are a number of broadly applicable measures that these specialty surgeons can report. For these reasons, we are finalizing our proposal to remove the Perioperative Care Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Back Pain Measures Group: Several commenters were concerned with the proposal to remove the Back Pain measures group, noting it would negatively impact physician anesthesiologists', pain medicine physicians' and physical therapists' ability to report. Other commenters supported the removal of some of the Back Pain measure group measures such as "Back Pain: Initial Visit" and "Back Pain: Physical Exam."

Response: The measures in this measure group reflect clinical concepts that do not add clinical value to PQRS. Specifically, the measures in this group are entirely clinical process measures that do not meaningfully contribute to improved patient outcomes, and CMS believes that removal of this measure group will not negatively impact physician anesthesiologists', pain medicine physicians', and physical therapists' ability to report. For these reasons, we are finalizing our proposal to remove the Back Pain Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Cardiovascular Prevention Measures Group: We proposed to remove the cardiovascular prevention measures group because a number of individual measures contained in this measures group are proposed to be removed from all PQRS program reporting options with the exception of EHR reporting. No comments were received about the removal of this measure group. For these reasons, we are finalizing our proposal to remove the Cardiovascular Prevention Measure Group from reporting in 2015 PQRS.

Comments on the proposed removal of the Ischemic Vascular Disease Measures Group: We proposed to remove the cardiovascular prevention measures group because a number of individual measures contained in this measures group are proposed to be removed from all PQRS program reporting options with the exception of EHR reporting. No comments were received

about the removal of this measure group. For these reasons, we are finalizing our proposal to remove the Ischemic Vascular Disease Measure Group from reporting in 2015 PQRS.

Comments on the proposed addition of the Acute Otitis Externa (AOE) Measures Group: One commenter supported the addition of this measure group.

Response: We did not receive any dissenting comments. For these reasons, we are finalizing our proposal to include the AOE measure group for reporting in 2015 PQRS.

Comments on the proposed removal of the Chronic Obstructive Pulmonary Disorder (COPD) Measures Group: We initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group (79 FR 40457). A new steward has been identified for the measures at risk, and for this reason we are not finalizing our proposal to remove this measures group in 2015.

Comments on the proposed removal of the Sleep Apnea Measures Group: We initially proposed to remove this measures group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk, and for this reason we are not finalizing our proposal to remove this measures group in 2015.

Comments on the proposed Rheumatoid Arthritis Measures Group: Commenters disagreed with CMS's proposal to add the Preventive Care and Screening: Influenza Immunization (PQRS #110) and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (PQRS #226) measures to the Rheumatoid Arthritis Measures Group for CY 2015. Commenters did not believe these measures provide substantial value to the specific clinical focus of this measures group. Instead, commenters recommend the addition of cross-cutting measure Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow (PQRS #128) and Pain Assessment and Follow-up (PQRS #131) to achieve the goal of six

measures while retaining clinical relevance. CMS agrees with commenters' suggestions and thus is not finalizing the proposal to add PQRS #110 and #226 to this measure group, but rather will add PQRS #128 and #131 to better support the clinical purpose of this measure group while meeting the six measure minimum requirement.

Tables 57 through 79 specify our final measures groups in light of the reasons stated in the proposed rule and the comments received. Please note that some measures groups were not addressed above. With respect to the measures groups that were not addressed above, we did not receive any comments on these proposed measures groups and are therefore finalizing the respective measures groups as proposed.

TABLE 57: Asthma Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0047/053	**Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting:** Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication	AMA-PCPI/NCQA
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	AMA-PCPI
0419/130	**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	CMS/QIP
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	AMA-PCPI
N/A/402	**Tobacco Use and Help with Quitting Among Adolescents:** Percentage of adolescents 13 to 20 years of age with a primary care visit during the measurement period for whom tobacco use status was documented and received help quitting if identified as a tobacco user.	NCQA / NCIQM
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 outisde 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/m^2 ; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m^2	CMS/QIP

TABLE 58: Acute Otitis Externa (AOE) Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0653/091	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations	AMA-PCPI
0654/093	**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	AMA-PCPI
0419/130	**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	CMS/QIP
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	CMS/QIP
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
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	CMS/QIP

TABLE 59: Cataracts Measures Group for 2015 and Beyond

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 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	CMS/QIP
0565/191	**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	AMA-PCPI/NCQA
0564/192	**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	AMA-PCPI/NCQA
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	AMA-PCPI
N/A/303	**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	AAO
N/A/304	**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	AAO
N/A/388	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vsitrectomy):** Rupture of the posterior capsule during anterior segment surgery requiring vsitrectomy	AAEECE/ACHS
N/A/389	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients who achieve planned refraction within +-1,0 D	AAEECE/ACHS

TABLE 60: Chronic Kidney Disease (CKD) Measures Group for 2015 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	AMA-PCPI/NCQA
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	AMA-PCPI
1668/121	**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	AMA-PCPI
N/A/122	**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]) and proteinuria with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care	AMA-PCPI
0419/130	**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	CMS/QIP
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	AMA-PCPI

TABLE 61: Chronic Obstructive Pulmonary Disorder (COPD) Measures Group for 2015 and Beyond

(Please note that CMS initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk and for this reason CMS is not finalizing its proposal to remove this measures group in 2015.)

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	AMA-PCPI/NCQA
0091/051	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA-PCPI
0102/052	**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/FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator	AMA-PCPI
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	AMA-PCPI
0043/111	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA
0419/130	**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	CMS/QIP
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	AMA-PCPI

TABLE 62: Coronary Artery Bypass Graft (CABG) Measures Group for 2015 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 CABG surgery who received an IMA graft	STS
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	CMS/QIP
0129/164	**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	STS
0130/165	**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	STS
0131/166	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (that is, any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	STS
0114/167	**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	STS
0115/168	**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. Please note that CMS had proposed to remove this measure from the program and thus this measure group as a result in the NPRM. However, as noted above in Table 55, CMS is not finalizing its proposal to remove this measure, and as such, the measure is not being removed from this measure group either.	STS

TABLE 63: Coronary Artery Disease (CAD) Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0067/006	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel	AMA-PCPI/ACCF/AHA
0070/007	**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	AMA-PCPI
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/m^2; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m^2	CMS/QIP
0419/130	**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	CMS/QIP
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	AMA-PCPI
N/A/242	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease 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	AMA-PCPI/ACCF/AHA

TABLE 64: Dementia Measures Group for 2015 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	AMA-PCPI/NCQA
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
N/A/285	**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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
N/A/288	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period	AMA-PCPI

TABLE 65: Diabetes Measures Group for 2015 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	NCQA
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	AMA-PCPI
0055/117	**Diabetes: Eye Exam**: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period	NCQA
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	NCQA
0056/163	**Diabetes: Foot Exam:** Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period	NCQA
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	AMA-PCPI

TABLE 66: General Surgery Measures Group for 2015 and Beyond

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 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	CMS/QIP
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	AMA-PCPI
N/A/354	**Anastomotic Leak Intervention:** Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery	ACS
N/A/355	**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	ACS
N/A/356	**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	ACS
N/A/357	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	ACS
N/A/358	**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	ACS

TABLE 67: Heart Failure (HF) Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0081/005	**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	AMA-PCPI/ACCF/AHA
0083/008	**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	AMA-PCPI/ACCF/AHA
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	AMA-PCPI/NCQA
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.	AMA-PCPI
0419/130	**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	CMS/QIP
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	AMA-PCPI

TABLE 68: Hepatitis C Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0395/084	**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) RNA testing was performed within 12 months prior to initiation of antiviral treatment	AMA-PCPI
0396/085	**Hepatitis C: 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	AMA-PCPI
0398/087	**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) RNA testing was performed between 4-12 weeks after the initiation of antiviral treatment	AMA-PCPI
0419/130	**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	CMS/QIP
0399/183	**Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV):** 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	AMA-PCPI
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	AMA-PCPI
N/A/401	**Screening for Hepatocellular Carcinoma (HCC) in patients with Hepatitis C 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	AGA/AASLD/AMA-PCPI
N/A/390	**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	AGA/AASLD/AMA-PCPI

TABLE 69: HIV/AIDS Measures Group for 2015 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	AMA-PCPI/NCQA
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	CMS/QIP
0405/160	**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	NCQA
0409/205	**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	AMA-PCPI/NCQA
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	AMA-PCPI
2082/338	**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	HRSA
2083/339	**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	HRSA
2079/340	**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	HRSA

TABLE 70: Inflammatory Bowel Disease (IBD) Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
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	AMA-PCPI
0043/111	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA
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	AMA-PCPI
N/A/270	**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 in the last reporting year	AGA
N/A/271	**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 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year	AGA
N/A/274	**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 for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA
N/A/275	**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 1 year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy	AGA

TABLE 71: Oncology Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0387/071	**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	AMA-PCPI/ASCO/NCCN
0385/072	**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	AMA-PCPI/ASCO/NCCN
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	AMA-PCPI
0419/130	**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	CMS/QIP
0384/143	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patients, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA-PCPI
0383/144	**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	AMA-PCPI
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	AMA-PCPI

TABLE 72: Optimizing Patient Exposure to Ionizing Radiation Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A/359	**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	AMA-PCPI
N/A/360	**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	AMA-PCPI
N/A/361	**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	AMA-PCPI
N/A/362	**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 entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study	AMA-PCPI
N/A/363	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Imaging 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	AMA-PCPI
N/A/364	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (for example, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors	AMA-PCPI

TABLE 73: Parkinson's Disease Measures Group for 2015 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	AMA-PCPI/NCQA
N/A/289	**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 (for example, medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (for example, 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	AAN
N/A/290	**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 (for example, psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually	AAN
N/A/291	**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	AAN
N/A/292	**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	AAN
N/A/293	**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 (for example, physical, occupational, or speech therapy) discussed at least annually	AAN
N/A/294	**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 (for example, non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually	AAN

TABLE 74: Preventive Care Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/039	**Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA-PCPI/NCQA
N/A/48	**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	AMA-PCPI/NCQA
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	AMA-PCPI
0043/111	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA
N/A/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	NCQA
0034/113	**Colorectal Cancer Screening:** Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer	NCQA
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/m^2; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m^2	CMS/QIP
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	CMS/QIP
AQA Adopted/173	**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** Please note that CMS had proposed to remove this measure from the program and thus this measure group as a result in the NPRM. However, as noted above in Table 55, CMS is not finalizing its proposal to remove this measure, and as such, the measure is not being removed from this measure group either.	AMA-PCPI
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	AMA-PCPI

TABLE 75: Rheumatoid Arthritis (RA) Measures Group for 2015 and Beyond

NQF/ PQRS	Measure Title and Description	Measure Developer
0054/108	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD)	NCQA
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/m^2; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m^2	CMS/QIP
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	CMS/QIP
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)	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI
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	AMA-PCPI

TABLE 76: Sinusitis Measures Group for 2015 and Beyond

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 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	CMS/QIP
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	CMS/QIP
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	AMA-PCPI
N/A/331	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Appropriate Use):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 7 days of diagnosis or within 10 days after onset of symptoms	AMA-PCPI
N/A/332	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Patients with Acute Bacterial Sinusitis:** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis	AMA-PCPI
N/A/333	**Adult Sinusitis: Computerized Tomography 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	AMA-PCPI

TABLE 77: Sleep Apnea Measures Group for 2015 and Beyond

(Please note that CMS initially proposed to remove this measure group contingent on the measure steward not being able to maintain certain measures contained in this measures group. A new steward has been identified for the measures at risk and for this reason CMS is not finalizing its proposal to remove this measures group in 2015.)

NQF/ PQRS	Measure Title and Description	Measure Developer
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/m^2; Age 18 – 64 years BMI ≥ 18.5 and < 25 kg/m^2	CMS/QIP
0419/130	**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	CMS/QIP
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	AMA-PCPI
N/A/276	**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	AMA-PCPI/NCQA
N/A/277	**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	AMA-PCPI/NCQA
N/A/278	**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	AMA-PCPI/NCQA
N/A/279	**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	AMA-PCPI/NCQA

TABLE 78: Total Knee Replacement (TKR) Measures Group for 2015 and Beyond

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 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	CMS/QIP
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	AMA-PCPI
N/A/350	**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 (or example, NSAIDS, analgesics, weight loss, exercise, injections) prior to the procedure	AAHKS
N/A/351	**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(for example, history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke) and Stroke	AAHKS
N/A/352	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS
N/A/353	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age or gender undergoing 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 prosthetic implant	AAHKS

e. Measures Available for Reporting in the GPRO Web Interface

We finalized the measures that are available for reporting in the GPRO web interface for 2014 and beyond in the CY 2013 PFS final rule (77 FR 69269). However, we proposed to remove and add measures in the GPRO web interface measure set as reflected in Tables 47 and 48 in the CY 2015 PFS proposed rule for 2015 and beyond (79 FR 40468). Specifically, Table 47 specified the measures we proposed to remove for reporting from the GPRO web interface, and Table 48 specified the measures we proposed to add for reporting in the GPRO web interface. CMS proposed to adopt Depression Remission at Twelve Months (NQF #0710) in the 2015 GPRO Web Interface reporting option for ACOs and group practices (79 FR 40469). This measure is currently reportable in the PQRS program through the EHR reporting option only and has not been tested using claims level data or sampling methodology. Depression Remission at Twelve Months (NQF #0710) requires a look-back period and a look-forward period possibly spanning multiple calendar years. Additionally, this measure requires

utilization of a PHQ-9 depression screening tool with a score greater than 9 and a diagnosis of depression/dysthymia to identify the beginning of the episode (initial patient population). Successful completion of the quality action for this measure looks for a PHQ-9 score of less than 5 at the twelve month mark (plus or minus 30 days) from the initial onset of the episode. CMS solicited comments regarding these proposals, and the comments are addressed in Tables 79 and 80.

TABLE 79: Measures Being Removed from the Group Practice Reporting Option Web Interface Beginning in 2015 and Beyond

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Programs
Measures Finalized as Proposed					
0097/ 046	Care Coordination/ Patient Safety	Patient Safety	**Medication Reconciliation:** Percentage of patients aged 65 years and older discharged from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented Several commenters agreed with CMS' proposal to remove this measure, noting "full medication reconciliation should be done at least annually with all patients." However, other commenters disagreed, indicating this measure "specifically evaluates the medication reconciliation during a time period when patients are most vulnerable during a time of transitions of care that may result in adverse consequences to the patient including preventable readmission to the hospital." However, CMS continues to believe NQF #0419 Documentation of Medications in the Medical Record is a more robust and broadly applicable measure. Furthermore, there have been implementation issues with this measure in the web interface, despite CMS believing this is a valuable measure. Finally, CMS is continuing to work to align the GPRO with the EHR Incentive Programs, and NQF #0419 is in the Incentive Program, whereas PQRS #046 is not. For these reasons, CMS is finalizing its proposal to remove this measure from reporting through the GPRO WI in 2015 PQRS and the Shared Savings Program.	AMA-PCPI/NCQA	
0074/ 197	Coronary Artery Disease	Effective Clinical Care	**Coronary Artery Disease (CAD): Lipid Control:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a minimum the prescription of a statin While some commenters disagreed with CMS's proposal to remove this measure "unless or until new measures that are more consistent with new and existing guidelines are put in place to replace them", several commenters supported the proposal to retire this and the two other lipid control measures listed as a result of new clinical guidelines released in 2013 by the American College of Cardiology and American Heart Association. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS and the Shared Savings Program.	AMA-PCPI/ ACCF/ AHA	

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: ● Diabetes Mellitus: High Blood Pressure Control. ● Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control. ● Diabetes Mellitus: Hemoglobin A1c Control (< 8%). ● Diabetes Mellitus: Tobacco Non-Use CMS proposed retiring 4 components of the 5 part diabetes composite measure as noted above. Specifically, commenters: ● Disagreed with removing the blood pressure component, noting "important that diabetic patients have their blood pressure and cholesterol monitored in order to prevent co-morbidities; if assessing quality of their care is folded into the general Medicare patient population, the focus on their care and desirable health care outcomes is effectively "watered down." However, other commenters supported this change noting "a measure that is based on a specific A1c level is no longer an accurate measure of a physician's ability to provide high quality care for their patients." CMS agrees this measure may no longer be the best measure of quality care in this area. Further, CMS continues to believe this measure is somewhat duplicative of the measure Controlling High Blood Pressure (NQF #0018) and that the diabetes measure may capture a subpopulation of the broader Controlling High Blood Pressure measure. ● Agreed with removing the LDL component as a result of new clinical guidelines released in 2013 by the American College of Cardiology and American Heart Association (https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf). ● Agreed with removing the Hemoglobin A1c Control (<8%) component, noting it is "too restrictive for a small cohort of patients and not restrictive enough for the majority of patients." ● Disagreed with removing the Tobacco Non-Use component, noting "this outcome based measure (as opposed to the screening and counseling measure) is not only a critical measure for diabetic best management, but removing it is stepping away from a known shared goal of moving towards outcome based measures." However, other commenters supported this change nothing that this measure, in addition to other measures, "were either duplicative of other measures or the guidelines for the measure have been changed." CMS continues to believe this component is somewhat duplicative of the Tobacco Screening and Cessation Counseling measure (NQF 0028) and NQF 0028 is more broadly applicable. For these reasons, CMS is finalizing its proposal to remove these four components of the diabetes composite measure from reporting in 2015 PQRS and the Shared Savings Program.	MNCM	

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Programs
0075/ 241	Ischemic Vascular Disease	Effective Clinical Care	**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) Commenters supported the proposal to retire this lipid control related measure because of the new clinical guidelines for statin treatment, as discussed for other LDL measures in this table. For this reason, CMS is finalizing its proposal to remove this measure from reporting in 2015 PQRS and the Shared Savings Program.	NCQA	MU2 Million Hearts
Measures Not Finalized as Proposed					
0068/ 204	Ischemic Vascular Disease	Effective Clinical Care	**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 CMS received comments about this measure being proposed for removal from the Web Interface for PQRS and the Shared Savings Program. Some commenters requested clarification of CMS's previous concern that the measure may not align with current guidelines when proposing its removal. After reviewing the measure further, we have determined the measure does not conflict with current guidelines the updated ATP-4 cholesterol guidelines, which have gone away from focusing on specific LDL targets, but do not impact this measure as previously thought. This measure is also a core measure for the Million Hearts Initiative. It is CMS's intent to maintain alignment with other quality reporting programs and HHS Initiatives. CMS also received comments supporting the removal of the measure from the Shared Savings Program, but requesting clarification of guideline changes impacting the measureTherefore, CMS will maintain alignment with the Million Hearts program and for this reason CMS is retaining this measure and it will be available for reporting through the GPRO WI in 2015 PQRS and the Shared Savings Program.	NCQA	MU2 Million Hearts

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Programs
0729/ 319	Diabetes Mellitus	Effective Clinical Care	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: ● Diabetes Mellitus: Daily Oral Aspirin or Antiplatelet Medication Use for Patients with Diabetes and Ischemic Vascular Disease CMS did not originally propose to remove this measure. However, this measure was reported in the PQRS as a component of the diabetes composite reportable via the GPRO Web Interface. We note that, while we did not originally propose to remove this measure, we proposed to remove all of the other components of the diabetes composite of which this measure was a part. Specifically, we proposed to remove the following components of the diabetes composite: • Diabetes Mellitus: High Blood Pressure Control. • Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control. • Diabetes Mellitus: Hemoglobin A I c Control (< 8%). • Diabetes Mellitus: Tobacco Non-Use Since we proposed to remove all other components of the diabetes composite listed above, we believe the public could reasonably foresee that we would remove this measure from the PQRS and Shared Savings Program measure set if all other components of the diabetes composite were removed. In addition, CMS believes the Daily Oral Aspirin component of this measure may be somewhat duplicative of PQRS #204 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic). Therefore, we are removing this measure from the PQRS measure set. To maintain alignment with PQRS and reduce reporting burden for ACOs, we are also removing this measure from the Shared Savings Program measure set. CMS believes that removing this measure will reduce burden on ACOs and allow them to improve their performance on the diabetes composite by reducing the number of measures included in the composite. Therefore, for the reasons stated above, we are removing this measure from the PQRS and Shared Savings Program measure set beginning in 2015	MNCM	

TABLE 80: New Measures That Will Be Available for Reporting by the Group Practice Reporting Option Web Interface Beginning in 2015 and Beyond

f. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

In the CY

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Program
Measures Finalized as Proposed					
0059/ 001	Diabetes Mellitus	Effective Clinical Care	**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 The Shared Savings Program and PQRS received many comments supporting removal of the Diabetes: Hemogolobin A1c control (<8 percent) (ACO-22), since <8 percent seems restrictive. CMS received some comments suggesting we move toward more outcome measures than process measures. CMS is finalizing its proposal to include this measure in the new Diabetes Management (DM) composite as a more appropriate A1c component for reporting in 2015 PQRS and the Shared Savings Program. This measure, Hemogolobin A1c Poor Control is being finalized because it addresses a clinically important area for diabetic patients and replaces the previous measure in the DM composite.	NCQA	MU2
0055/ 117	Diabetes Mellitus	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period Several commenters supported the addition of this measure to the GPRO WI for PQRS and the Shared Savings Program, noting eye exams are an important part of quality care for diabetic patients. CMS also received some comments suggesting that we not finalize additional process measures and questioning the improvement to outcomes, noting while "foot and eye exams are an important part of good diabetes care, we recommend that they not replace the current outcomes measures in the Diabetes Composite measure set." CMS agrees foot and eye exams are a valuable addition that reflect good diabetes care. Please see Table 79 for additional discussion of the rationale for the removal of the previous diabetes composite. CMS is finalizing its proposal to include this measure in the new Diabetes Management composite in the GPRO WI for reporting in 2015 PQRS and Shared Savings Program due to the clinical importance of the measure and alignment of programs.	NCQA	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Program
0419/ 130	Care Coordination/ Patient Safety	Patient Safety	**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 While some commenters disagreed with the addition of this measure, others suggested medication reconciliation should be performed at all office visits and not just those visits occurring after an inpatient discharge. Furthermore, the steward of CARE-1 (PQRS #46) Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility indicated this measure is not appropriate for the GPRO WI reporting mechanism. Some commenters recommended limiting documentation of current medications to only the last visit due to potential reporting burden. We disagree with the commenters who disagree with the addition of this measure. We believe this measure adequately captures an important aspect of patient safety – the need to understand a patient's current medications. We believe documenting current medications is key to determining the most appropriate care for a patient. With respect to the commenters who believed that medication reconciliation should be performed on all office visits, please note that the title and description of the measure does not limit this measure to documentation after an inpatient discharge. With respect to a measure steward's concern that this measure is not appropriate for the GPRO WI reporting mechanism, we disagree with the measure steward. As we note above, we believe this measure is appropriate for the GPRO WI as it captures an important aspect of patient safety. Based on the comments received and for the reasons stated above, CMS is finalizing its proposal to replace PQRS #46 with PQRS #130 Documentation of Current Medications in the Medical Record for reporting in the GPRO WI in 2015 PQRS and Shared Savings Program and will consider reporting burden in finalizing specifications for GPRO reporting.	CMS/QIP	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Program
0710/ 370	Mental Health	Effective Clinical Care	**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. Several commenters for PQRS and the Shared Savings Program expressed concern over use of the PHQ-9, indicating not all practices use this tool. CMS appreciates commenter feedback and concerns regarding issues with the use of PHQ-9. CMS recognizes there may be EPs reporting who do not currently use this tool and because of the look back period may not be able to implement this tool in time for the next reporting period, and as such CMS is considered adjustments to how this measure will be reported, specifically for the Shared Savings Program. CMS continues to believe this Depression Remission measure represents an important outcome. Depression management is particularly important due the effects on patient adherence with treatment for other chronic conditions. For these reasons, CMS is finalizing its proposal to make this measure reportable through the GPRO WI in 2015 PQRS and the Shared Savings Program. Given the comments and concerns raised regarding the use of the PHQ-9 tool and providing ACOs with time to make necessary adjustments for implementation, the measure will be designated as pay-for-reporting under the Shared Savings Program for all 3 years of an ACO's first agreement period, as specified in the program's final measure set.	MNCM	MU2
Measures Not Finalized as Proposed					
0067/ 006	Coronary Artery Disease	Effective Clinical Care	**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. Commenters agreed with the addition of this measure, but recommended testing the composite and maintaining as only pay-for-reporting for the Shared Savings Program. Other commenters did not agree with including this measure due to concerns that the composite has not been reviewed by NQF and has not been tested before implementation. CMS agrees this measure needs to be tested as part of the composite prior to implementation and as such, CMS is not finalizing its proposal to include this measure for reporting in for the PQRS GPRO web interface and Shared Savings Program.	AMA-PCPI/ ACCF/ AHA	MU2
0070/ 007	Coronary Artery Disease	Effective Clinical Care	**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 LVEF < 40% who were prescribed beta-blocker therapy Some commenters agreed with the addition of this measure while others did not agree with including this measure and suggested testing and submission to NQF. We also believe this measure is topped out. Therefore, CMS is not finalizing its proposal to include this measure for reporting for the PQRS and Shared Savings Program GPRO web interface.	AMA-PCPI/ ACCF/ AHA	MU2

NQF/ PQRS	GPRO Module	NQS Domain	Measure and Title Description[¥]	Measure Steward	Other Quality Reporting Program
0056/ 163	Diabetes Mellitus	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 While several commenters supported the addition of this measure, many commenters did not support the inclusion of this process measure and suggested further testing of the composite as well as identifying the link to improved outcomes. Furthermore, CMS believes the measures that are being finalized for the Diabetes Composite represent a robust, outcome focused set of measures with room for quality improvement. Therefore, CMS is not finalizing its proposal to make this measure reportable through the GPRO WI in 2015 PQRS and the Shared Savings Program.	NCQA	MU2
N/A/ 242	Coronary Artery Disease	Effective Clinical Care	**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 Some commenters agreed with CMS' proposal to include this measure in the GPRO WI. However, most commenters did not support including the measure due to lack of NQF endorsement and the reporting burden/challenges if the measure is finalized. Due to the comments received not supporting the measure due to reporting burden, CMS is not finalizing its proposal to include this measure for reporting in 2015 PQRS and Shared Savings Program GPRO web interface.	AMA-PCPI/ ACCF/ AHA	
0729/ 319	Diabetes Mellitus	Effective Clinical Care	**Diabetes Composite: Optimal Diabetes Care:** Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: ● Diabetes Mellitus: Daily Oral Aspirin or Antiplatelet Medication Use for Patients with Diabetes and Ischemic Vascular Disease As discussed in Table 79 above, CMS believes the Daily Oral Aspirin component of this measure may be somewhat duplicative of PQRS #204, ACO-30 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic). Furthermore, upon further review and with CMS's intent to maintain alignment with other quality reporting programs and limit the number of potentially duplicative measures that may cause additional reporting burden, CMS is removing this measure from the PQRS and Shared Savings Program measure sets.	MNCM	

f. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

In the CY 2014 PFS final rule with comment period, we finalized the CG-CAHPS survey available for reporting under the PQRS for 2014 and beyond (78 FR 74750 through 74751), to which we

are now referring as the CAHPS for PQRS. Please note that, in the CY 2014 PFS final rule with comment period, we classified the CAHPS for PQRS survey under the care coordination and communication NQS domain. We noted that this was an error on our part, as the CAHPS for PQRS survey has typically been classified under the Person and Caregiver-Centered Experience and Outcomes domain as the CAHPS for PQRS survey assesses beneficiary experience of care and outcomes. Therefore, as we indicated in Table 21 of the CY 2015 proposed rule, we proposed to reclassify the CAHPS for PQRS survey under the Person and Caregiver-Centered Experience and Outcomes domain. We invited public comment on this proposal. Please note that the comments on this proposal are addressed in Table 54, where the domain change for CAHPS for PQRS as well as other PQRS measures is indicated.

6. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a QCDR for 2014 and Beyond for Individual Eligible Professionals

For the measures which eligible professionals participating in a QCDR must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the ATRA, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a QCDR. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the ATRA, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a QCDR, by specifying that for measures used by a QCDR, sections 1890(b)(7) and 1890A(a) of the Act shall not apply, and measures endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act may be used.

In the CY 2014 PFS final rule with comment period, we finalized requirements related to the parameters for the measures that would have to be reported to CMS by a QCDR for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS (78 FR 74751 through 74753). Although we did not propose to remove any of the requirements we finalized related to these parameters, we proposed to modify the following parameters we finalized in the CY 2014

PFS final rule with comment period related to measures that may be reported by a QCDR (79 FR 40472 through 40473):

- The QCDR must have at least 1 outcome measure available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost).

As we proposed that for an eligible professional to meet the criterion for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment, the eligible professional must report on at least 3 outcome measures or, in lieu of 3 outcome measures, at least 2 outcome measures and 1 resource use, patient experience of care, or efficiency/appropriate use measure, we modified this requirement to conform to this satisfactory participation criterion. Therefore, we proposed that a QCDR must have at least 3 outcome measures available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). In lieu of having 3 outcome measures available for reporting, the QCDR must have at least 2 outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure (79 FR 40473). We solicited and received the following comments on this proposal:

Comment: As the majority of commenters opposed our proposal to require the reporting of 3 outcomes measures to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment, for the same reasons, the majority of commenters also opposed our proposal to require that a QCDR must have at least 3 outcome measures available for reporting, or, in lieu of 3 outcome measures, a QCDR have at least 2 outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure. The commenters believed this proposed requirement was overly burdensome for QCDRs.

Response: We responded to the commenters' concerns regarding our proposal to require the reporting of 3 outcomes measures to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment at III.K.3.a. For the same reasons discussed in that section, we are modifying our proposal to require that a QCDR must have at least 3 outcome measures available for reporting, or, in lieu

of 3 outcome measures, a QCDR have at least 2 outcome measures available for reporting and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure. To correspond with the final criteria for the satisfactory participation for the 2017 PQRS payment adjustment, for 2015 and beyond, we are modifying this proposal to require that a QCDR have at least 2 outcome measures available for reporting. An outcomes measure is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). In lieu of having 2 outcomes measures available for reporting, the QCDR must at least have 1 outcome measure available for reporting and at least 1 resource use, patient experience of care, efficiency/appropriate use measure, or patient safety measure. We believe this is an appropriate modification, as QCDRs that only have the ability to report 1 outcome measure may still report 1 outcome measure as long as the QCDR has another measure (resource use, patient experience of care, efficiency/appropriate use measure, or patient safety measure) in another domain available for reporting.

We proposed to define resource use, patient experience of care, or efficiency/appropriate use measures in the following manner (79 FR 40473):

- A resource use measure is a measure that is a comparable measure of actual dollars or standardized units of resources applied to the care given to a specific population or event, such as a specific diagnosis, procedure, or type of medical encounter. We did not receive any comments on this proposed definition of a resource use measure. As such, we are finalizing this definition of a resource use measure as proposed.

- A patient experience of care measure is a measure of person- or family-reported experiences (outcomes) of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations. We did not receive any comments on this proposed definition of a patient experience of care measure. As such, we are finalizing this definition of a patient experience of care measure as proposed.

- An efficiency/appropriate use measure is a measure of the appropriate use of health care services (such as diagnostics or therapeutics) based upon evidence-based guidelines of care, or for which

the potential for harm exceeds the possible benefits of care. We did not receive any comments this proposed definition of an efficiency/appropriate use measure. As such, we are finalizing this definition of an efficiency/appropriate use measure as proposed.

Please note that, for purposes of meeting the criteria for satisfactory participation in a QCDR, we allow QCDRs to report on any measure if it meets the measure parameters we finalize. We noted that we would allow and encourage the reporting of the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS) through a QCDR.

Finally, in the CY 2014 PFS final rule with comment period, we stated that a QCDR must provide to CMS descriptions and narrative specifications for the measures for which it will report to CMS by no later than March 31, 2014. In keeping with this timeframe, we proposed that a QCDR must provide to CMS descriptions for the measures for which it will report to CMS for a particular year by no later than March 31 of the applicable reporting period for which the QCDR wishes to submit quality measures data. We solicited and received the following comments on this proposal:

Comment: Commenters believed that it was reasonable to require a QCDR to provide to CMS descriptions and narrative specifications for the measures for which it will report to CMS by no later than March 31, 2014.

Response: We appreciate the commenters' feedback. Based on the comments received, we are finalizing our proposal to require that a QCDR must provide to CMS descriptions for the measures for which it will report to CMS for a particular year by no later than March 31 of the applicable reporting period for which the QCDR wishes to submit quality measures data. For example, if a QCDR wishes to submit quality measures data for the 2017 PQRS payment adjustment (the 12-month reporting period of which occurs in 2015), the QCDR must provide to CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2015. The descriptions must include: name/title of measures, NQF # (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure. The narrative specifications provided must be similar to the narrative specifications we provide in our measures list, available at

http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2014_PQRS_IndClaimsRegistry_MeasureSpecs_SupportingDocs_12132013.zip.

Related to this proposal, we proposed that, 15 days following CMS approval of these measure specifications, the QCDR must publicly post the measures specifications for the measures it intends to report for the PQRS using any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year. We believe providing this information will further aid in creating transparency of reporting. We solicited and received the following comment on this proposal:

Comment: Some commenters supported this proposal, as the commenters believe it was reasonable to require that this information be made available to the public. The commenters supported our proposal to defer to the QCDR in terms of what platform and in what manner this data may be made available to the public. Some commenters opposed this proposal based on their concerns that the public reporting requirement was overly burdensome and urged CMS to delay requiring the posting of measures data until the measures have been tested for validity and reliability. The commenters believed that CMS should not make substantial changes in the QCDR requirements, as the QCDR option is new and the entities need time to familiarize themselves with the QCDR option before new requirements are established. One commenter preferred public reporting of QCDR quality measures data through a single site so that information would be easily accessible and people seeking this information would not be forced to look through multiple sites.

Response: With respect to the commenters who opposed this proposal and urged us not to make additional changes to the QCDR option while entities become more familiar with this option, we understand the commenters' concerns. However, we believe that transparency of data is a key component of a QCDR option. Furthermore, in the CY 2014 PFS final rule, while we did not finalize our proposal that a QCDR have a plan to publicly report quality measures data, we noted that we encouraged QCDRs "to move towards the public reporting of quality measures data" and stated that "[w]e plan to establish such a requirement in the future and will revisit this proposed requirement as part of CY 2015

rulemaking" (78 FR 74471). Therefore, we believe that QCDRs were on notice that we would finalize a requirement to make quality measures data available to the public. With respect to the commenter that preferred this information to be posted on a single site, we note that the Physician Compare website will provide quality measures data information on eligible professionals participating in QCDRs. Therefore, while the QCDRs are free to provide this information elsewhere, the Physician Compare website will serve as a point where all information will be accessible. Based on the reasons we stated above and in the proposed rule, we are finalizing our proposal to require that, 15 days following CMS approval of these measure specifications, a QCDR must publicly post the measures specifications for the measures it intends to report for the PQRS using any public format it prefers. Immediately following posting of the measures specification information, the QCDR must provide CMS with the link to where this information is posted. CMS will then post this information when it provides its list of QCDRs for the year.

7. Informal Review

In the CY 2013 PFS final rule with comment period (77 FR 69289), we established that "an eligible professional electing to utilize the informal review process must request an informal review by February 28 of the year in which the payment adjustment is being applied. For example, if an eligible professional requests an informal review related to the 2015 payment adjustment, the eligible professional would be required to submit his/her request for an informal review by February 28, 2015." As stated in the CY 2013 PFS final rule with comment period, we believed this deadline provided ample time for eligible professionals and group practices after their respective claims begin to be adjusted due to the payment adjustment. However, because PQRS data is used to establish the quality composite of the VM, we believe it is necessary to expand the informal review process to allow for some limited corrections of the PQRS data to be made. Therefore, we proposed to modify the payment adjustment informal review deadline to within 30 days of the release of the feedback reports. For example, if the feedback reports for the 2016 payment adjustment (based on data collected for 2014 reporting periods) were released on August 31, 2015, an eligible professional or group practice would be required to submit a request for an informal review by September 30, 2015. We believe that by being able to notify eligible professionals and group practices of CMS' decision on the informal review request much earlier than we would have

been able to do with the previous informal review request deadline we can provide a brief period for an eligible or group practice to make some limited corrections to its PQRS data. This resubmitted data could then be used to make corrections to the VM calculations, when appropriate.

The PQRS regulations at §414.90(m)(1) currently require an eligible professional or group practice to submit an informal review request to CMS within 90 days of the release of the feedback reports. Therefore, we proposed to revise §414.90(m)(1) to require the request of the informal review within 30 days of release of the feedback reports.

Regarding the eligible professional's or group practice's ability to provide additional information to assist in the informal review process, we proposed to provide the following limitations as to what information might be taken into consideration:

- CMS would only allow resubmission of data that was submitted using a third-party vendor using the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms. Therefore, CMS would not allow resubmission of data submitted via claims, direct EHR, or the GPRO web interface reporting mechanisms. We are limiting resubmission to third-party vendors, because we believe that third-party vendors are more easily able to detect errors than direct users.

- CMS would only allow resubmission of data that was already previously submitted to CMS. Submission of new data – such as new measures data not previously submitted or new data for eligible professionals for which data was not submitted during the original submission period – would not be accepted.

- For any given resubmission period, CMS would only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies. For example, the resubmission period immediately following the informal review period for the 2017 PQRS payment adjustment would only allow resubmission for data previously submitted for the 2017 PQRS payment adjustment reporting periods occurring in 2015.

As such, we proposed to add §414.90(m)(3) to reflect this proposal as follows: (3) If, during the informal review process, CMS finds errors in data that was submitted using a third-party vendor using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may

allow for the resubmission of data to correct these errors. (i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms. (ii) CMS will only allow resubmission of data that was already previously submitted to CMS. (iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

We invited public comment on these proposals. The following is summary of the comments we received regarding on these proposals.

Comment: Several commenters opposed our proposal to change the amount of time an eligible professional or group practice would have to submit an informal review request to 30 days. One commenter stated that it was necessary to have a longer timeframe, as accessing PQRS feedback reports can be extremely cumbersome and time-intensive. The commenters believed that 30 days was an insufficient amount of time to access, analyze, and identify errors in the PQRS feedback reports. Some of these commenters urged CMS to extend the request period to 60 or 90 days in lieu of 30 days.

Response: We understand that this provides eligible professionals and group practices with a much shorter timeline with which to submit an informal review request. We also understand the commenters' concerns regarding having to access and analyze the feedback reports as well as submitting an informal review request within 30 days. As we stated in the proposed rule, it is necessary to shorten the timeline in order to be allow for the resubmission of data, if applicable to the eligible professional or group practice. However, given these concerns, we will increase the amount of time in which eligible professionals and group practices may submit an informal review request. In order to finalize our proposal to allow for the resubmission of data, it is necessary to receive all informal review requests within 60 days of the release of the feedback reports. At this time, we believe the 60-day deadline still provides us with enough time to allow for the resubmission of data. However, should we find that more time is needed to process resubmissions, we reserve the right to propose further changes to this deadline in future rulemaking. Therefore, for the reasons stated above and in the proposed rule, we are finalizing our proposal to modify §414.90(m)(1) to indicate the payment adjustment informal review deadline to within 60 days of the release of the feedback reports beginning in 2015.

Comment: Several commenters generally supported our proposal to allow for resubmission of data.

Response: We appreciate the commenters' support for this proposal. Based on the support for this proposal and for the reasons we stated in the proposed rule, we are finalizing our proposal to allow for resubmission of data as proposed. As we proposed, we are providing the following limitations as to what information might be taken into consideration:

- CMS would only allow resubmission of data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms. Therefore, CMS would not allow resubmission of data submitted via claims, direct EHR, or the GPRO web interface reporting mechanisms. We are limiting resubmission to third-party vendors, because we believe that third-party vendors are more easily able to detect errors than direct users.

- CMS would only allow resubmission of data that was already previously submitted to CMS. Submission of new data – such as new measures data not previously submitted or new data for eligible professionals for which data was not submitted during the original submission period – would not be accepted.

- For any given resubmission period, CMS would only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies. For example, the resubmission period immediately following the informal review period for the 2017 PQRS payment adjustment would only allow resubmission for data previously submitted for the 2017 PQRS payment adjustment reporting periods occurring in 2015.

Because of the comments received and for the reasons stated above and in the proposed rule, we are finalizing our proposal to modify the payment adjustment informal review deadline to within 60 days of the release of the feedback reports. In addition, to allow resubmission of data, we are finalizing our proposal, as proposed, to add §414.90(m)(3) as follows: (3) If, during the informal review process, CMS finds errors in data that was submitted using a third-party vendor using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to

correct these errors. (i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms. (ii) CMS will only allow resubmission of data that was already previously submitted to CMS. (iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

L. Electronic Health Record (EHR) Incentive Program

The 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 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.

For CY 2012 and subsequent years, §495.8(a)(2)(ii) requires an EP to successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable.

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 noted it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions 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.

Since finalizing this proposal, we have received feedback from stakeholders regarding the difficulty and expense of having to test and recertify CEHRT products to the most recent version of the electronic specifications for the CQMs. Although we still believe EPs should test and certify their products to the most recent version of the electronic specifications for the CQMs when feasible, we understand the burdens associated with this requirement. Therefore, to eliminate this added burden, we proposed that, beginning in CY 2015, EPs would not be required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Please note that, although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs.

In the CY 2014 PFS final rule with comment period, we established the requirement that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs (78 FR 74756). We solicited and received the following public comments on these proposals:

Comment: The majority of commenters supported our proposal not to require EPs to recertify their EHR products to the most recent version of the eCQMs. One commenter opposed this proposal, stating that if we did not require recertification some products run the risk of not being able to perform critical Stage 2 functions such as secure messaging between patients and providers, offering patients the ability to view, download, and transmit their own health information, and improving care transitions with a summary of care record for transitions and referrals.

Response: We appreciate the commenters' support for this proposal. With respect to the commenter who opposed this proposal, we agree that it is important to recertify as frequently as

possible for the reasons the commenter stated. However, at this time, we understand that requiring recertification to the most recent version of the electronic specifications for the CQMs, which could occur annually, may be overly burdensome and time-consuming for providers. Please note that this proposal was limited to EPs and not intended to apply to eligible hospitals (EHs) or critical access hospitals. Based on the comments received and for the reasons stated in the proposed rule, we are finalizing our proposal 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.

Additionally, we noted in the proposed rule that, with respect to the following measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), a substantive error was discovered in the June 2013 version of this electronically specified clinical quality measure (79 FR 40474). If an EP chooses to report this measure electronically under the EHR Incentive Program in CY 2014, the prior, December 2012 version of the measure, which is CMS140v1, must be used (78 FR 74757). In the proposed rule (79 FR 40474), we stated that because a more recent and corrected version of this measure has been developed, we will require the reporting of the most recent, updated version of the measure Breast Cancer Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), if an EP chooses to report the measure electronically in CY 2015.

In the EHR Incentive Program Stage 2 final rule, we established CQM reporting options for the Medicare EHR Incentive Program for CY 2014 and subsequent years that include one individual reporting option that aligns with the PQRS's EHR reporting option (77 FR 54058) and two group reporting options that align with the PQRS GPRO and Medicare Shared Savings

Program (MSSP) and Pioneer ACOs (77 FR 54076 to 54078). In the CY 2014 PFS final rule with comment period, we finalized two additional aligned options for EPs to report CQMs for the Medicare EHR Incentive Program for CY 2014 and subsequent years with the intention of minimizing the reporting burden on EPs (78 FR 74753 through 74757). One of the aligned options finalized in the CY 2014 PFS final rule with comment period (78 FR 74754 through 74755) is a reporting option for CQMs for the Medicare EHR Incentive Program under which EPs can submit CQM information using qualified clinical data registries, according the definition and requirements for qualified clinical data registries established under the PQRS.

The second aligned option finalized in the CY 2014 PFS final rule with comment period (78 FR 74755 through 74756) is a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 under which EPs who are part of a Comprehensive Primary Care (CPC) initiative practice site that successfully reports at least nine electronically specified CQMs across three 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.

The 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 will 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 483 CPC practice sites across 7 health care markets in the U.S. More details on the CPC initiative can be found at http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html.

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). We proposed to retain the group reporting option for CPC practice sites as finalized in the CY 2014 PFS final rule, but to relax the requirement for the CQMs to cover three domains. Instead, we proposed that, for CY 2015 only, under this group reporting option, the CPC practice site must report a minimum of nine CQMs from the CPC subset, and the nine CQMs reported must cover at least 2 domains, although we strongly encouraged practice sites to report across more domains if feasible. Although the requirement to report across three domains is important because the domains are linked to the National Quality Strategy and used throughout CMS quality programs, the CPC practice sites are required to report from a limited number of CQMs that were selected for the EHR Incentive Program and are focused on a primary care population. Therefore, these CPC practice sites may not have measures to select from that cover three domains. Additionally,

CPC practice sites are assessed for quality performance on measures other than electronically specified CQMs which do cover other National Quality Strategy domains. We invited public comment on this proposal.

The following is a summary of the comments we received regarding our proposal on the group reporting option for CPC practice sites.

Comment: A few commenters indicated general support for relaxing the domain requirement for the primary care physicians, indicating providers should be able to select the measures most applicable to their population.

Response: We appreciate the support for this proposal. The CPC CQM set targets a primary care patient population and therefore is appropriate for reporting by CPC practice sites in the model.

Comment: One commenter opposed relaxing the reporting requirements for CPC practice sites to only report 2 domains instead of 3. The commenter indicated consumers and purchasers want to see measures across these domains reported electronically. The commenter believed CPC practice sites have sufficient measures to choose from to report 9 measures that cover 3 domains.

Response: The CPC initiative is a model tested by the Center for Medicare and Medicaid Innovation. As such, CPC includes specific quality measure reporting requirements for each CPC practice site to be eligible to participate in any Medicare shared savings, which is a component of the model. The quality reporting requirements include reporting on a subset of the CQMs selected for the EHR Incentive Program beginning in CY 2014.

The CPC measure subset includes a total of 11 measures, of which 7 fall in the clinical process/effectiveness domain, 3 in the population health domain, and 1 in the safety domain. We proposed to reduce the number of domains required to at least 2 domains to allow CPC practice

sites that would be unable to obtain in their EHR the one safety CQM in the CPC measure subset to meet the MU CQM requirement. This would provide CPC practice sites an opportunity to successfully report to the CPC model and satisfy the CQM reporting component of meaningful use, so they would not have to report quality measures twice to both CPC and the Medicare EHR Incentive Program.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the proposal to reduce the required number of domains for CY 2015 only as proposed.

M. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has 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 implementing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

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, we established the quality performance standards that ACOs must meet to be eligible to share in savings that are generated (76 FR 67870 through 67904). Quality performance measures are submitted by ACOs through a CMS web interface, currently the group practice reporting option (GPRO) web interface, calculated by CMS from internal and claims data, and collected through a patient and caregiver experience of care survey.

Consistent with the directive under section 1899(b)(3)(C) of the Act, we believe the existing Shared Savings Program regulations incorporate a built in mechanism for encouraging ACOs to improve care over the course of their 3-year agreement period, and to reward quality improvement over time. During the first year of the agreement period, ACOs can qualify for the maximum sharing rate by completely and accurately reporting all quality measures. After that, ACOs must meet certain thresholds of performance, which are currently phased in over the course of the ACO's first agreement period, and are rewarded for improved performance on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings (or, for ACOs subject to performance-based risk that demonstrate losses, lower rates of shared losses). In this way, the quality performance standard increases over the course of the ACO's agreement period.

Additionally, we have made an effort to align quality performance measures, submission methods, and incentives under the Shared Savings Program with the PQRS. Eligible professionals participating in an ACO may qualify for the PQRS incentive payment under the

Shared Savings Program or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the GPRO web interface.

Since the November 2011 final rule establishing the Shared Savings Program was issued, we have revisited certain aspects of the quality performance standard in the annual PFS rulemaking out of a desire to ensure thoughtful alignment with the agency's other quality incentive programs that are addressed in that rule. Specifically, we have updated our rules to align with PQRS and the EHR Incentive Program, and addressed issues related to benchmarking and scoring ACO quality performance (77 FR 69301 through 69304; 78 FR 74757 through 74764). This year, as part of the CY 2015 Physician Fee Schedule proposed rule, we addressed several issues related to the Shared Savings Program quality performance standard and alignment with other CMS quality initiatives. Specifically, we revisited the current quality performance standard, proposed changes to the quality measures, and sought comment on future quality performance measures. We also proposed to modify the timeframe between updates to the quality performance benchmarks, to establish an additional incentive to reward ACO quality improvement, and to make several technical corrections to the regulations in subpart F of Part 425.

1. Existing Quality Measures and Performance Standard

As discussed previously, section1899(b)(3)(C) of the Act states that the Secretary may 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 that consists of 33 measures. These 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. Although the patient experience of care survey used for the Shared Savings Program includes the core CG-CAHPS modules, this patient experience of care survey also includes some additional modules. Therefore, we will refer to the patient experience of care survey that is used under the Shared Savings Program as CAHPS for ACOs. The measures span four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. The measures collected through the GPRO web interface are also used to determine whether eligible professionals participating in an ACO qualify for the 2013 and 2014 PQRS incentive payment or avoid the PQRS payment adjustment for 2015 and subsequent years. Eligible professionals in an ACO may qualify for the PQRS incentive payment or 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.

In selecting the 33 measure set, we balanced a wide variety of important considerations. Given that many ACOs were expected to be newly formed organizations, in the November 2011 Shared Savings Program final rule (76 FR 67886), we concluded that ACO quality measures should focus on discrete processes and short-term measurable outcomes derived from administrative claims and limited medical record review facilitated by a CMS-provided web interface to lessen the burden of reporting. Because of the focus on Medicare FFS beneficiaries, our measure selection emphasized prevention and management of chronic diseases that have high impact on these 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.

At this time, we continue to believe it is most appropriate to focus on quality measures that directly assess the overall quality of care furnished to FFS beneficiaries. The set of 33 measures that we adopted in the November 2011 Shared Savings Program final rule includes measures addressing patient experience, outcomes, and evidence-based care processes. Thus far, we have not included any specific measures addressing high cost services or utilization since we believe that the potential to earn shared savings offers an important and direct incentive for ACOs to address utilization issues in a way that is most appropriate for their organization, patient population, and local healthcare environment. We note that while the quality performance standard is limited to these 33 measures, the performance of ACOs is measured on many more metrics and ACOs are informed of their performance in these areas. For example, an assessment of an ACO's utilization of certain resources is provided to the ACO via quarterly reports that contain information such as the utilization of emergency services or the utilization of CTs and MRIs.

As we have stated previously (76 FR 67872), our principal goal in selecting quality measures for ACOs was to identify measures of success in the delivery of high-quality health care at the individual and population levels. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, selected the 33 measures with 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, for example, ACO#11, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment.

In selecting the final set of 33 measures, we sought to include both process and outcome measures, including patient experience of care (76 FR 67873). 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 continue to believe it is important to have a combination of both process and outcomes measures. We note, however, that as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we may also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures over time.

Therefore, we viewed the 33 measures adopted in the November 2011 Shared Savings Program final rule as a starting point for ACO quality measurement. As we stated in that rule (67 FR 67891), we plan to modify the measures in future reporting cycles to reflect changes in practice and improvements in quality of care and to continue aligning with other quality reporting programs and will add and/or retire measures as appropriate through the rulemaking process. In addition, we are working with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date. We note that we must 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.

In the November 2011 Shared Savings Program final rule (76 FR 67873), we combined care coordination and patient safety into a single domain to better align with the National Quality

Strategy and to emphasize the importance of ambulatory patient safety and care coordination. We also intended to continue exploring ways to best capture ACO care coordination metrics and noted that we would consider adding new care coordination measures for future years (67 FR 67877).

2. Changes to the Quality Measures Used in Establishing Quality Performance Standards that ACOs must meet to be Eligible for Shared Savings

a. Background and Proposal.

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 Physician Fee Schedule proposed rule, we proposed a number of measure additions, deletions and other revisions that we believed would be appropriate for the Shared Savings Program. An overview of changes we proposed is provided in Table 50 of the proposed rule (79 FR 40479 through 40481) which lists the measures that we proposed would be used to assess ACO quality under the Shared Savings Program starting in 2015. To summarize, we proposed to add 12 new measures and retire eight measures. We also proposed to rename the EHR measure in order to reflect the transition from an incentive payment to a payment adjustment under the EHR Incentive Program and to revise the component measures within the Diabetes and CAD composites. In total, we proposed to use 37 measures for establishing the quality performance standard that ACOs must meet to be eligible for shared savings. Although the total number of measures would increase from the current 33 measures to 37 measures under this proposal, we stated we did not anticipate that this would increase the reporting burden on ACOs because the increased number of measures is accounted for by

measures that would be calculated by CMS using administrative claims data or from a patient survey. The total number of measures that the ACO would need to directly report through the CMS website interface would actually decrease by one, in addition to removing redundancy in measures reported.

Finally, as part of the proposed changes, we proposed to replace the current five component diabetes composite measure with a new four component diabetes composite measure. In addition, we proposed to replace the current two component coronary artery disease composite measure with a new four component coronary artery disease composite measure. Under this proposal, 21 measures would be reported by ACOs through the GPRO web interface and scored as 15 measures.

Below, we summarize and group comments received on these proposals by first responding to general comments on our proposals and then by the method of data submission for the measure as listed in Table 50 of the proposed rule (79 FR 40479 through 40481) (that is, survey, claims, EHR incentive program, and the CMS web interface). In order to align the measures submitted through the CMS web interface with the PQRS and VM programs, we discuss specific comments in response to the proposed changes to the measures submitted through the CMS web interface with the comments received for these same measures for the PQRS and the VM programs. See Tables 79 and 80 in section III.K., for a discussion of and response to these comments.

General Comment: In addition to the comments that focus on individual measures, we received many general comments about the quality performance measures used in the Shared Savings Program. For example, we received many comments supporting the alignment between ACO, PQRS and VM quality measures and an increased focus on outcomes-based quality

measures. Some commenters objected to the net increase in measures, believing there is underlying burden for providers even for claims-based measures. Additionally, many ACOs did not support the proposed new measures, suggesting, for example, they would be unnecessary because of the incentives inherent to the Shared Savings Program, or that, in general, the new proposed measures are inadequately defined, tested or benchmarked. These ACOs believed that many of the proposed new measures address clinical issues beyond an ACO's control and therefore should not be added. Other concerns about the new measures were that they would require substantial change in clinical practice, would substantially add to the reporting burden, and/or are questionably related to improving care quality and/or patient outcomes.

Other commenters supported adding the new measures. One commenter, for example, stated that "the expanded measures are important utilization and management measures that our developing ACO would have likely considered and built into our ACO Cost, Utilization, and Risk dashboard anyway. From a clinical and system standpoint, these additions are key components of better managing avoidable utilization and costs. They are measures we would want to know regardless of the Proposed Rule." MedPAC suggested that CMS move quality measurement for ACOs, MA plans, and FFS Medicare in the direction of a small set of population-based outcome measures, such as potentially preventable inpatient hospital admissions, emergency department visits, and readmissions.

Response: We continue to believe it is appropriate to add, remove, and modify quality measures for the Shared Savings Program to reflect changes in clinical practice and for other program needs. We want to minimize any additional burdens this could create for ACOs and their ACO participants and ACO providers/suppliers. Therefore, we agree with the comments in support of the alignment between ACO, PQRS and VM for the quality measures submitted

through the CMS web interface, and an increased focus on outcomes-based quality measures. We disagree with those ACOs that suggested certain proposed new measures would be unnecessary because of the incentives inherent to the Shared Savings Program. Instead, we agree with the commenter who noted that such measures can be important utilization and management tools that many ACOs may consider and build into their own internal monitoring systems as a way to help manage avoidable utilization and costs. Further, we believe certain proposed new measures highlight the value of discussions with patients about their care.

b. Survey based measure:

- CAHPS Stewardship of Patient Resources. This measure is one of the unscored survey measures currently collected in addition to the seven scored survey measures that are already part of the current set of 33 measures under the Shared Savings Program. Information on the unscored survey measure modules is currently shared with the ACOs for informational purposes only. The Stewardship of Patient Resources measure asks the patient whether the care team talked with the patient about prescription medicine costs. The measure exhibited high reliability during the first two administrations of the CAHPS survey, and during testing, the beneficiaries that participated in cognitive testing said that prescription drug costs were important to them. We proposed to add Stewardship of Patient Resources as a scored measure in the patient experience domain because we believe, based on testing, that this is an important factor for measuring a beneficiary's engagement and experience with healthcare providers. We also proposed that the measure would be phased into pay for performance as we plan to do for other new measures, using a similar process to the phase in that was used for the scored measure modules in the survey that are currently used to assess ACO quality performance.

Comment: Some commenters supported the proposed addition of this measure, agreeing

that discussing the cost of medications is important to assess the possibility that medication costs may be a barrier to care or that the measure may be an indicator of a patient's satisfaction with the care he or she is receiving. Other commenters questioned how this discussion leads to a plan of action or a modified plan of treatment to improve care if the patient is unable to pay for the medication. These commenters asked us to further explain how we envision this measure improving patient care. Some believe it would be reasonable to include this measure under pay for reporting, but that additional discussions with the community would be needed in order to establish an appropriate benchmark for this measure, as this is a relatively new measure. Some thought that physician discussions with patients regarding medication cost would be appropriate for "high tier," costly medications, but would be of questionable value relative to measuring patient-centered, quality care delivery for more frequently prescribed, lower cost, generic medications and/or the extent to which patients take medications as prescribed. Some commenters suggested that it would be unnecessary and/or burdensome to add this measure. For example, commenters indicated that physicians do not and cannot know the co-pays for each drug under each insurance plan and product and that there would be tremendous patient dissatisfaction when inaccurate pricing or cost information is provided to the patient by the provider. Some commenters believe this measure is unnecessary since encouraging adherence to medications is a key strategy for ACOs to reduce avoidable costs, and inability to afford medications is a key barrier to adherence, so ACOs already have an incentive to discuss the cost of medications with their patients.

Response: This measure asks patients whether any health care provider spoke to them about their prescription medication costs and does not require that physicians know the co-pays for each drug under each insurance plan and product. Additionally, discussing this topic with

beneficiaries can lead a clinician to understand whether and how the beneficiary may struggle with payment for medications, a factor that can affect adherence to prescribed regimens. We can therefore envision a scenario where, once the issue is identified, a clinician participating in an ACO could inform and educate the beneficiary about less expensive options, such as the use of generic medications, or about available community resources, as part of the ACO's care coordination processes required under §425.112(b)(4). This in turn could directly improve the quality of care the beneficiary receives by improving medication adherence and leading to greater beneficiary engagement. Because this measure is already part of the CAHPS survey, we do not believe it will increase reporting burden for the ACO. The CAHPS survey question is available in the CAHPS Survey for ACOs Quality Assurance Guidelines on the CAHPS for ACOs website. As discussed below, because this is a new measure, the measure will be pay-for-reporting for the first two reporting periods it is in use for all ACOs, regardless of the phase-in schedule to pay-for-performance, in order to provide time for the development of an appropriate benchmark.

Final Decision: We are finalizing our proposed addition of the CAHPS: Stewardship of Patient Resources measure. After the measure has been used in the program under pay for reporting for two reporting periods, it will be pay-for-reporting for the first performance year of an ACO's first agreement period and pay-for-performance for the ACO's second and third performance years. We continue to believe that it is important for physicians and others to discuss the beneficiary's perspective on the cost of medications because is important to assess the possibility that medication costs may be a barrier to care. The measure exhibited high reliability during the first two administrations of the CAHPS survey, and during testing, the

beneficiaries that participated in cognitive testing said that prescription drug costs were important to them.

c. Claims Based Measures to be Computed by CMS

- Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM). We proposed to add a 30-day all cause skilled nursing facility (SNF) readmission measure. CMS is the measure steward for this claims-based measure, which is under review at NQF under NQF #2510. This measure estimates the risk-standardized rate of all-cause, unplanned, hospital readmissions for patients who have been admitted to a SNF within 30 days of discharge from a prior inpatient admission to a hospital, CAH, or a psychiatric hospital. The measure is based on data for 12 months of SNF admissions. We believe this measure would help fill a gap in the current Shared Savings Program measure set and would provide a focus on an area where ACOs are targeting care redesign. ACOs and their ACO participants often include post-acute care (PAC) settings and the addition of this measure would enhance the participation of and alignment with these facilities. Even when the ACO does not include post-acute facilities formally as part of its organization, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure would be calculated from claims, there would not be a burden on ACOs to collect this information.

Comment: A number of commenters supported including the measure and/or the concept to align the incentives of ACOs and SNFs to lower their readmission rates. Some provided suggestions to further refine the measure, such as to use a risk-adjusted measure of potentially avoidable readmissions for SNFs. Although MedPAC recommended that CMS consider a risk-

adjusted, potentially avoidable readmission measure for SNFs, they did support the addition of a SNF readmission measure because of the importance of post-acute care management and care transitions between settings in improving beneficiary care. Another commenter supported the measure but encouraged delay until such time as Medicare readmission policy links a portion of SNF payments to their readmission rates so that SNFs would bear risk/penalty equal to that of other providers in order to incent readmissions reduction. Some commenters believe that it is unnecessary and duplicative to add this quality measure since it is an inherent part of the Shared Savings Program that an ACO will be penalized through a reduction in shared savings if it has a high rate of readmissions. They also argue that ACOs that use SNFs for higher-acuity patients could see an increase in SNF readmission rates and thus be inappropriately penalized. A commenter suggested ACO scores will be inappropriately affected when beneficiaries return to an ACO participant hospital after being discharged to a SNF that is not participating in the ACO. In such cases, an ACO may be unable to achieve the same level of collaboration needed to affect change as compared to ACOs that include one or more SNFs as ACO participants or ACO providers/suppliers. Concern was also expressed regarding the ability of ACOs to consistently monitor psychiatric hospital discharges since federal laws limit the use and disclosure of documentation regarding drug and substance abuse as well as mental health therapies. These commenters recommend removing psychiatric hospital admissions from this measure since ACOs currently do not receive mental health claims data and should not be held accountable for measures for which they are not able to collect and monitor data over the performance period. Operational concerns were also raised including data lags and that ACOs can only derive raw admissions/readmission rates from the monthly claims files and the commenters believe these rates are not useful for improving performance against benchmarks unless CMS provides the

algorithm to apply the appropriate risk adjustment. These commenters indicate that ACOs face significant challenges in monitoring performance when reliable risk-adjusted rates of admissions and readmissions are not provided on a regular basis.

Response: We appreciate the numerous thoughtful comments. We disagree with commenters that this measure is unnecessary and duplicative because we continue to believe that including this measure would reinforce the importance of coordinating the care of beneficiaries across hospital and SNF sites of care. We have previously expressed our expectation that ACOs coordinate the care of beneficiaries across these sites regardless of whether there are any post-acute care (PAC) providers participating in the ACO (§425.112(b)(4)). Even when the ACO does not include post-acute facilities formally as ACO participants or ACO providers/suppliers, ACO providers/suppliers furnish other services that have the potential to affect PAC outcomes. Thus, this measure would emphasize the importance of coordinating the care of beneficiaries across these sites of care. Additionally, because this measure is calculated from claims, there would not be a reporting burden on ACOs to collect this information. We appreciate the recommendations that we use a risk-adjusted, potentially avoidable SNF readmission measure, however, there is currently no such measure available for use. We note that the SNF 30-day all-cause readmission measure does exclude planned readmissions using a similar methodology to ACO-8 Risk-Standardized, All Condition Readmission. Unplanned readmission rates do provide ACOs with useful information to better coordinate care and work toward reducing the risk of readmissions for all patients, including patients coming from a SNF. Further, contrary to the assertion of some commenters, we note that the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). See the Department's guidance on the HIPAA

Privacy Rule and sharing information related to mental health, available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html. Thus, ACOs that request claims data under §425.704 for purposes of their own health care operations or the health care operations of their covered entity ACO participants and ACO providers/suppliers, in accordance with HIPAA requirements, already receive information about mental health therapies as part of those data sets.

Final Decision: We are finalizing our proposal to add this 30-day all-cause SNF readmission measure. After the measure has been used in the program under pay for reporting for two reporting periods, the measure will be pay-for-reporting in the first two performance years of an ACO's first agreement period and will transition to pay-for-performance in the final year of the ACO's agreement period. We believe this measure will help fill a gap in the current Shared Savings Program measure set and will provide a focus on an area where ACOs are targeting care redesign.

- All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart Failure (HF) and Multiple Chronic Conditions. We proposed to add three new measures to the Care Coordination/Patient Safety domain. The three new measures are for: all-cause unplanned Admissions for Patients with Diabetes Mellitus (DM), all-cause unplanned Admissions for Patients with Heart Failure (HF) and all-cause unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). These three measures are under development through a CMS contract with Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (CORE) to develop quality measures specifically for ACO patients with heart failure, diabetes, and multiple chronic conditions. We believe that these measures are important to promote and assess ACO quality as it relates to chronic condition inpatient admission because

these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional burden on ACOs.

The following is a summary of the comments we received regarding our proposal to add these three new claims-based measures for All-Cause Unplanned Admissions for Patients with DM, HF and MCC.

Comment: We received a wide variety of comments in response to the proposal to add these claims-based measures. Many commenters supported the use of claims-based outcome measures to reduce reporting burden for providers, however, concerns were raised regarding the lack of NQF endorsement. Some commenters supported adding one or more of these measures, agreeing that chronic condition inpatient admissions are major causes for unplanned admissions and that the addition of one or more of these measures would support the ACOs' efforts to improve care coordination. For example, a few commenters supported the addition of a measure for All Cause Unplanned Admission for Patients with Multiple Chronic Conditions as all efforts to manage chronic disease may help lead to better patient outcomes and control cost. Another commenter supported the measures but preferred collapsing them into one measure of potentially avoidable hospitalizations, because of concern that the proposed condition-specific measures will be statistically unreliable and subject to random variation that will limit their usefulness in distinguishing ACOs' actual performance. In addition, some commenters urged CMS to ensure the measures are adjusted for planned readmissions, unrelated readmissions and socio-demographic status. Other commenters supported applying these measures in the Shared Savings Program as pay for reporting only at this time since these measures are still under

development, accepted target rates are not available and the measures are not yet endorsed by NQF. Commenters requested additional definition of what "other multiple chronic conditions" would be measured. MedPAC supported an increase of outcome measures. Finally, some commenters believe it is not possible to comment on measures that are still under development, and questioned the added benefit of including these measures since ACOs have an inherent incentive to avoid or reduce unplanned hospital admissions.

Response: We continue to believe that these measures are important to promote and assess ACO quality because these chronic conditions are major causes for unplanned admissions and the addition of these measures will support the ACOs' efforts to improve care coordination for beneficiaries with these chronic conditions. These measures are claims-based, and therefore, we do not expect that they would impose any additional reporting burden on ACOs. Many concerns were raised regarding the lack of NQF endorsement, but CMS intends on submitting all three measures to NQF for review in the future. Draft measure specifications were made available to the public during the measure development comment period during the spring and summer of 2014. CMS will provide final measure specifications to the public when available (typically in the early part of the performance year). The MCC measure cohort definition aligns with the NQF MCC Measurement Framework, which defines patients with MCCs as people "having two or more concurrent chronic conditions that…act together to significantly increase the complexity of management, and affect functional roles and health outcomes, compromise life expectancy, or hinder self-management."[11] The MCC measure cohort of chronic conditions

[11] National Quality Forum (NQF). Multiple Chronic Conditions Measurement Framework. 2012; http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71227

includes conditions such as, but not limited to, Acute Myocardial Infarction, Stroke, and Chronic Obstructive Pulmonary Disease.

Final Decision: After considering the comments received in response to our proposal to add these three measures, we will add the All-Cause Unplanned Admissions for Patients with MCC, HF, and DM measures as pay-for-reporting for two performance years. After this time, the measure will be pay-for-reporting for the first two performance years for new ACOs in their first agreement period before transitioning to pay for performance in performance year three. We believe that it is important to include these measures in the Shared Savings Program measure set since they were specifically developed for ACO populations and move the quality performance standard under the Shared Savings Program toward more outcome-based measures. DM, HF, and MCCs affect a large volume of Medicare beneficiaries and can result in high costs due to poorly coordinated care. As a result, these chronic conditions are a focus of many ACO care redesign activities. Finally, these measures are claims-based and therefore do not impose an additional burden on ACOs for data reporting.

d. Measure submitted through the EHR incentive program:

- Percent of PCPs who Successfully Meet Meaningful Use Requirements.

Because downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program, we proposed to modify the name and specifications for ACO #11 Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment so that it more accurately depicts successful use and adoption of EHR technology in the coming years. We note this measure would continue to be doubly weighted.

Comment: We received a range of comments regarding this proposal. Some agreed that it is necessary to rename the measure given that the EHR Incentive Program begins its transition

to a payment adjustment effective in 2015. Some of the commenters, while agreeing with the proposed change, also provided additional specification suggestions such as to exclude certain physicians, such as hospitalists, from the denominator of this measure, stating that hospitalists are not PCPs when providing observation services. Another commenter requested that CMS clarify "the interaction of the Medicaid Meaningful Use program and the MSSP" and "the impact to non-PCP EPs". Another commenter requested that CMS make the list of EPs available to ACOs intermittently throughout the performance year to aid ACOs in ensuring that all EPs attest in a timely manner. A commenter questioned why this measure in its current form is limited only to PCPs, as opposed to all EPs that are ACO providers/suppliers. Others were concerned that there appeared to be no opportunity to exclude physicians such as those who retired, died, moved out the country, from the denominator of this measure. Finally, there were a number of commenters that suggested the measure should be dropped and not renamed, since it is a process measure and the commenters believe that this measure has no direct relationship to the quality of patient care.

Response: We continue to believe, as do a number of commenters, that this is an important measure that should be retained and renamed given that downward adjustments to Medicare payments will begin in 2015 under the EHR Incentive Program. We appreciate the suggestions from commenters that agree with the proposed change and provided additional specification suggestions. We are not persuaded by commenters that suggest this measure should be removed from the quality performance standard for the Shared Savings Program. On the contrary, we believe the measure directly supports the adoption and meaningful use of certified EHR technology, which is an important tool to support change in the health care delivery system including the steps being taken by ACOs to improve the quality and efficiency

of care. The measure specifications will continue to align with the EHR Incentive Program definitions of hospital-based providers and will exclude observation services, accordingly. The measure specifications include Medicare and Medicaid eligible PCPs. Practitioners other than PCPs are not included in the measure at this time in efforts to focus on the meaningful use of certified EHRs in the provision of primary care services. This measure aligns with other HHS initiatives that support the adoption and meaningful use of certified EHR technology. For example, the HHS Office of the National Coordinator for Health Information Technology and CMS are managing $27 billion in funding from the American Recovery and Reinvestment Act of 2009 and other sources to promote the adoption of electronic health records (EHR) in hospitals and doctor's offices[12]. More than 75 percent of eligible health care professionals, and over 90 percent of eligible hospitals, have already qualified for EHR incentive payments for using certified EHR technology. Retaining this measure in the quality performance standard for the Shared Savings Program will help provide an additional and appropriate incentive to reinforce the adoption and meaningful use of certified EHR technology. Finally, performance on this measure is determined using EHR Incentive Program data and due to the EHR Incentive Program timelines and data collection, CMS will not be able to provide lists of EPs to ACOs throughout the performance year.

Final Decision: After consideration of the comments received, we are finalizing the proposal to modify the name and specifications of ACO-11 to the Percent of PCPs who successfully meet MU requirements.

e. Measures submitted through the CMS web interface

[12] http://www.hhs.gov/news/press/2014pres/09/20140916a.html

To align with PQRS, we proposed to add several measures submitted through the CMS web interface that we believed were appropriate for the ACO quality performance standard. The measures we proposed to add were:

- Depression Remission at Twelve Months (NQF #0710).
- Diabetes Measures for Foot Exam and Eye Exam (NQF #0056 and #0055).
- Coronary Artery Disease (CAD): Symptom Management.
- Coronary Artery Disease (CAD): Beta Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%) (NQF #0070).
- Coronary Artery Disease (CAD): Antiplatelet Therapy (NQF #0067).
- Documentation of Current Medications in the Medical Record (NQF #0419).

Additionally, we identified a number of the existing measures submitted through the CMS web interface that have not kept up with clinical best practice, are redundant with other measures that make up the quality performance standard, or that could be replaced by similar measures that are more appropriate for ACO quality reporting. For the reasons specified in the proposed rule, we proposed to no longer collect data on the following measures, and these measures would no longer be used for establishing the quality performance standards that ACOs must meet to be eligible to share in savings:

- ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility.
- ACO #22, Diabetes Composite measure: Hemoglobin A1c control (<8 percent).
- ACO #23, Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).
- ACO #24, Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).
- ACO #25, Diabetes Composite: Tobacco Non-use (NQF #0729).

- ACO #29, Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100 mg/dl) (NQF #0075).
- ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068).
- ACO #32, Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering LDL Cholesterol (NQF #74).

Finally, given these proposed changes, we also proposed updates and revisions to the Diabetes and CAD Composite measures. We proposed that the Diabetes Composite include the following measures:

- ACO #26: Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease.
- ACO #27: Diabetes: Hemoglobin A1c Poor Control.
- ACO #41: Diabetes: Foot Exam.
- ACO #42: Diabetes: Eye Exam.

We further proposed that the CAD Composite include the following measures:

- ACO #33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).
- ACO #43: Antiplatelet Therapy.
- ACO #44: Symptom Management.
- ACO #45: Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%).

We solicited comment on these composite measures and whether there are any concerns regarding the calculation of a composite score. Given the general concerns around composite

measures and their use, we also solicited comment on how we combine and incorporate component measure scoring for the composite.

Comment: Most commenters supported the proposed removal and replacement of measures that may not align with current clinical guidelines or that appear to overlap with other measures currently in the measure set. At least one commenter specifically opposed removal of ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068) and the LDL measures, stating that there is disagreement on guidelines among professional organizations. Others expressed concern about the number of proposed changes that will require ACOs, in turn, to make changes to their internal processes and their EHRs to facilitate data collection. Some commenters raised general clinical or other methodological concerns about individual proposed measures submitted through the CMS web interface. Our detailed responses to those comments can be found in Table 79 of section III.K. of this final rule with comment period.

We do, however, wish to note some specific comments relevant to our final policy decisions with respect to the quality performance measures used in the Shared Savings Program: (1) Commenters noted that the Patient Health Questionnaire 9 (PHQ-9) is specified for use in the Depression Remission measure (proposed ACO # 40), and that this tool is only one of several options available to practitioners. These commenters suggested not adding this measure until ACOs have had the opportunity to uniformly phase in the use of the PHQ-9 in order to meet the measure specification requirements. Additionally, commenters suggested that their ability to perform well on this measure may be limited if they cannot access the PHQ-9 score data from mental health care providers. (2) Many commenters did not support the proposed addition of the CAD: Symptom Management measure (proposed ACO # 44), stating they believe the measure

lack primary care focus and that there are potential challenges in data collection. CMS also received a comment supporting the proposed addition of the CAD: Antiplatelet Therapy measure (proposed ACO # 43), however, this commenter recommended that if added, the measure only be used for pay-for-reporting. (3) Some commenters did not support the retirement of the 4 Diabetes Composite measures and 1 CAD Composite measure proposed to be removed due to the resources already invested in reporting these 5 measures. (4) CMS received comments suggesting that the quality performance standard under the Shared Savings Program should focus on broader categories of measures (such as preventive health measures) that are generalizable across providers and care settings, rather than measures that target specific providers or care settings.

Response: We continue to believe that the quality performance measures used in the Shared Savings Program should reflect current clinical guidelines. We appreciate the commenters' agreement with our proposed changes to remove and replace measures that are not in adherence with current clinical guidelines. In response to comments, included in Table 79 in section III.K , we will retain ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068). We note that we erroneously made the assertion that this measure conflicts with current clinical guidelines. Therefore, due to the clinical importance of the measure, the measurement gap it addresses, and its alignment with the Million Hearts Campaign and PQRS, we will retain this measure.

Given the concerns raised by commenters, included in Table 80 of section III.K, regarding our proposal to use PHQ-9 for the Depression Remission measure, we will not finalize our proposal that the measure would be phased-in to pay-for-performance during the second and third performance years of an ACO's first agreement period. We will, however, finalize our

proposal to use the measure to assess ACO quality, but only as pay-for-reporting for all three performance years of an ACO's first agreement period. We believe this approach will provide flexibility for ACOs to continue to use tools other than the PHQ-9, while providing the opportunity for ACOs to begin adopting this tool without harming their ability to achieve full points on the measure. Additionally, as noted above, the HIPAA Privacy Rule generally provides the same protections for mental health information as it does for all protected health information (with the exception of psychotherapy notes). We therefore do not believe there would be any unusual impediments to accessing the information required for reporting of this particular measure.

After consideration of the comments received and in order to align with the final measures that will be used in the PQRS program, we will not finalize the CAD: Symptom Management (proposed ACO – 44) and CAD: Antiplatelet Therapy (proposed ACO – 43) measures for the Shared Savings Program. See section III.K, Table 79, for comment discussion and response.

We believe it is important to make changes in the measures used to assess ACO quality to address the statutory mandate in section 1899(b)(3)(A) of the Act which requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, reflect current clinical practice, promote high quality care, and alignment with PQRS and National Quality Strategy. We therefore disagree with commenters that internal operational challenges that arise from changes in the measure set outweigh the benefit of such changes.

After considering the comments received regarding the proposed new measures, we are finalizing our proposal to add the following new measures that will be submitted by the ACO through the CMS web interface:

- Documentation of Current Medications in the Medical Record (NQF #0419).
- Depression Remission at Twelve Months (NQF #0710).
- Diabetes Measures for Eye Exam (NQF #0055).

For the reasons stated in section III.K., we decline to finalize our proposals to add the following measures:

- Diabetes: Foot Exam (NQF #0056)
- CAD: Antiplatelet Therapy (NQF #0067)
- CAD: Symptom Management
- CAD: Beta-Blocker Therapy – Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVSD) (NQF #0070)

We are not finalizing our proposal to add the CAD: Antiplatelet Therapy (NQF #0067) measure and instead will keep the measure it was designed to replace, ACO #30, Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068) because we have determined that it does not conflict with clinical guidelines, remains clinically important, addresses a measurement gap, and aligns with the Million Hearts Campaign and PQRS. We believe that retention of this measure in lieu of the proposed Antiplatelet Therapy measure will additionally reduce burden on ACOs that would otherwise need to revise their data collection processes to accommodate this change.

Additionally, we are finalizing our proposal to remove certain measures from the ACO quality performance standard including the following:

- ACO #12, Medication Reconciliation after Discharge from an Inpatient Facility
- ACO #22, Diabetes Composite measure: Hemoglobin A1c control (<8 percent).
- ACO #23, Diabetes Composite: Low Density Lipoprotein (<100) (NQF #0729).

- ACO #24, Diabetes Composite: Blood Pressure (<140/90) (NQF #0729).
- ACO #25, Diabetes Composite: Tobacco Non-use (NQF #0729).
- ACO #29, Ischemic Vascular Disease: Complete Lipid Profile and LDL Control (<100 mg/dl) (NQF #0075).
- ACO #32, Coronary Artery Disease (CAD) Composite: Drug Therapy for Lowering LDL Cholesterol (NQF #74).

Finally, given these changes, we are revising the Diabetes Composite to include the following measures:

- ACO #27: Diabetes: Hemoglobin A1c Poor Control (NQF #0059).
- ACO #42: Diabetes: Eye Exam (NQF #0055).

Although not previously proposed, in order to align with PQRS and in response to commenter concerns about using this measure outside the composite, we are removing ACO #26, Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease. While we believe the measure may be valid apart from the composite, we are swayed by the concerns raised by commenters as discussed in Table 79 in section III.K. We believe removing ACO-26 is consistent with our proposals to align with the PQRS program and remove redundancy of measures within the Shared Savings Program measure set. In addition, we believe removing this measure will reduce reporting burden for ACOs and may also help to improve performance on the diabetes composite. We also note that the removal of this measure would additionally alleviate some redundancy with ACO #30 Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic (NQF #0068) which we are retaining for the reasons discussed above.

The CAD Composite will be removed since there is only one CAD measure remaining.

We believe that the final measure set as adopted in this final rule is appropriate for purposes of the ACO quality performance standard and in order to align with changes being made to the PQRS for the reasons specified above and in Tables 79 and 80 in section III.K. Additionally, we believe that our final decision to remove certain measures will improve alignment with best practices and reduce reporting burden for ACOs.

f. Summary of Changes to the ACO Quality Measures

We are finalizing the ACO quality performance measures as follows. In total, we will use 33 measures to establish the quality performance standards that ACOs must meet to be eligible for shared savings. Although the number of measures in the measure set remains at 33, we are reducing the number of measures reported through the CMS web interface by 5 to reduce burden. In addition, as discussed in section III.K., we are also reducing the number of patients ACOs are required to report on for each measure. This change will also reduce the burden of quality reporting for ACOs. The new measures will be pay for reporting for the first two performance years for all ACOs. After this initial period, the measures will be phased in to pay-for-performance over the course of an ACO's first agreement period with the exception of Depression Remission at 12 Months which will stay at pay-for-reporting for all three performance years.

Specifically, we are finalizing the following changes to the Shared Savings Program quality measure set (see Table 81 for a list of the final measures and for further details of phase in to pay-for-performance during the agreement period):

- Add the CAHPS: Stewardship of Patient Resources measure as pay-for-reporting in the first performance year of an ACO's first agreement period and pay-for-performance in the second and third performance years.

- Add SNF 30-Day All-Cause Readmission measure and All-Cause Unplanned Admissions measures for Patients with Multiple Clinical Conditions, Heart Failure, and Diabetes as pay-for-reporting for the first two years of an ACO's first agreement period before transitioning to pay for performance in performance year three.
- Add Depression Remission at 12 Months (NQF #0710) measure as pay-for-reporting for all three performance years of an ACO's first agreement period.
- Replace ACO-12 Medication Reconciliation (NQF #0097) with "Documentation of Current Medications in the Medical Record" (NQF #0419).
- Add Diabetes: Eye Exam (NQF #0055)
- Modify name and specifications of ACO-11 from Percent of PCPS who successfully Qualify for an EHR Incentive Program Payment to the Percent of PCPs who Successfully Meet MU Requirements.

In addition, we are finalizing the retirement of 6 of the 7 measures we proposed to delete because they do not align with updated clinical guidelines or are similar to existing measures (ACO-22, 23, 24, 25, 29, and 32). We are not finalizing our proposal to remove ACO-30 Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic and are removing ACO-26 Diabetes Mellitus: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease due to comments received and for the reasons discussed above and in section III.K, Table 79.

We are also not finalizing the following proposed measures, but instead will continue to consider them for the future given the measurement gaps and high-cost, high-volume conditions these measures address for the quality performance standard as discussed in Table 79 in section III.K:

- Diabetes: Foot Exam (NQF #0056)
- CAD: Antiplatelet therapy (NQF #0067)
- CAD: Symptom management
- CAD: Beta-blocker therapy – prior Myocardial Infarction (MI) or LVSD (NQF #0070)

As a result, we will no longer have a CAD composite in the measure set and will only have 1 CAD measure in the Clinical Care in the At-Risk Population domain (ACO# 33: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)).

An overview of the changes we are finalizing is provided in Table 81, which lists the measures that will be used to assess ACO quality under the Shared Savings Program starting with the 2015 performance year.

TABLE 81: 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	X	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)	X	NQF #TBD CMS	Claims	R	R	**P**
	ACO - 36	All-Cause Unplanned Admissions for Patients with Diabetes	X	NQF#TBD CMS	Claims	R	R	**P**
	ACO -37	All-Cause Unplanned Admissions for Patients with Heart Failure	X	NQF#TBD CMS	Claims	R	R	**P**
	ACO -38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	X	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**

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase In R – Reporting P – Performance PY1	PY2	PY3
	ACO -39	Documentation of Current Medications in the Medical Record	X	NQF #0419 CMS	CMS Web Interface	R	**P**	**P**
	ACO - 13	Falls: Screening for Future Fall Risk		NQF #0101 NCQA	CMS Web Interface	R	**P**	**P**
AIM: Better Health for Populations								
Preventive Health	ACO - 14	Preventive Care and Screening: Influenza Immunization		NQF #0041 AMA-PCPI	CMS Web Interface	R	**P**	**P**
	ACO – 15	Pneumonia Vaccination Status for Older Adults		NQF #0043 NCQA	CMS Web Interface	R	**P**	**P**
	ACO – 16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up		NQF #0421 CMS	CMS Web Interface	R	**P**	**P**
	ACO – 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	**P**	**P**
	ACO – 18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	**P**	**P**
	ACO – 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	**P**
	ACO – 20	Breast Cancer Screening		NQF #NA NCQA	CMS Web Interface	R	R	**P**
	ACO - 21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented		CMS	CMS Web Interface	R	R	**P**
Clinical Care for At Risk Population - Depression	ACO – 40	Depression Remission at Twelve Months	X	NQF #0710 MNCM	CMS Web Interface	R	**R**	**R**
Clinical Care for At Risk Population - Diabetes		Diabetes Composite (All or Nothing Scoring):		CMS Composite				
	ACO -27	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	X	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**

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
Clinical Care for At Risk Population – Coronary Artery Disease	ACO - 33	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%)		NQF # 0066 ACC	CMS Web Interface	R	R	**P**

The current quality scoring methodology is explained in the regulations at §425.502 and in the preamble to the November 2011 final rule (76 FR 67895 through 67900). As a result of the additions, deletions, and revisions to the quality measure set being made in this final rule, each of the four domains will include the following number of quality measures (See Table 82 for details.):

- Patient/Caregiver Experience of Care – 8 measures
- Care Coordination/Patient Safety – 10 measures
- Preventive Health – 8 measures
- At Risk Population – 6 measures (including 5 individual measures and a 2-component diabetes composite measure)

Table 82 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes under these changes. Otherwise, the current methodology for calculating an ACO's overall quality performance score will continue to apply. Table 83 provides the measures that are retired/replaced.

TABLE 82: 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	8	8 measures	16	25%
At-Risk Population	7	5 individual measures, plus a 2-component diabetes composite measure, scored as one.	12	25%
Total in all Domains	33	32	66	100%

TABLE 83: Shared Savings Program Measures Retired/Replaced

Notes	Domain	Measure Title	NQF Measure #/ Measure Steward	Method of Data Submission	Pay for Performance Phase In R = Reporting P=Performance Performance Performance Year 1	Performance Year 2	Year 3
ACO #12 Replaced	Care Coordination/ Patient Safety	**Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility**	NQF #97 AMA-PCPI/NCQA	GPRO Web Interface	R	**P**	**P**
ACO #22 Retired	At Risk Population - Diabetes	**Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent)**	NQF #0729 MN Community Measurement	GPRO Web Interface	R	**P**	**P**
ACO #23 Retired	At Risk Population - Diabetes	**Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100)**	NQF #0729 MN Community Measurement	GPRO Web Interface	R	**P**	**P**
ACO #24 Retired - Redundant Measure	At Risk Population - Diabetes	**Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90**	NQF #0729 MN Community Measurement	GPRO Web Interface	R	**P**	**P**
ACO #25 Retired - Redundant measure	At Risk Population - Diabetes	**Diabetes Composite (All or Nothing Scoring): Tobacco Non Use**	NQF #0729 MN Community Measurement	GPRO Web Interface	R	**P**	**P**
ACO # 26 Retired - redundant measure	At Risk Population – Diabetes	**Diabetes Composite: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease**		GPRO Web Interface	R	**P**	**P**
ACO #29 Retired	At Risk Population – Ischemic Vascular Disease	**Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl**	NQF #75 NCQA	GPRO Web Interface	R	**P**	**P**
ACO #32 Retired	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL-Cholesterol**	NQF #74 CMS (composite) / AMA-PCPI (individual component)	GPRO Web Interface	R	R	**P**

We believe that these modifications to the quality measure set for the Shared Savings Program will further enhance the quality of care patients receive from ACO participants and

ACO providers/suppliers, better reflect clinical practice guidelines, streamline measures reporting, and enhance alignment with PQRS and the EHR Incentive Program.

g. Effective date and phase in of quality measures.

Proposal: We proposed that these measures changes would become effective beginning with the 2015 reporting period, and the 2015 performance year (PY). We also proposed that all quality measures would be phased in for ACOs with 2015 start dates according to the phase-in schedule in Table 81. We proposed that ACOs with start dates before 2015 would be responsible only for complete and accurate reporting of the new measures for the 2015 performance year and then responsible for either reporting or performance on measures according to the phase in schedule.

Comment: Most commenters did not separately provide comments on this specific proposal regarding the effective date for measure changes but addressed the general issue as part of their comments on individual measures or related issues, especially with respect to the effective date for benchmarking purposes. However, a number of commenters disagreed with the proposal to move certain new measures to pay for performance after only one year of pay for reporting. They suggested that an additional year of pay for reporting would be needed in order to adequately and fairly set benchmarks for pay for performance, especially for measures that have not been previously tested in any large scale health system and may be newly or not yet accredited by the National Quality Forum (NQF).

Response: We are finalizing our proposal that quality measures will become effective for the Shared Savings Program quality performance standard beginning in 2015 and the phase-in schedule indicated in Table 81. Additionally, we are convinced by commenters that believe that an additional year of pay for reporting is needed by CMS and ACOs to fully implement new measures. Therefore, each new measure will be pay-for-reporting for its first two reporting

periods in use. This additional time will help to ensure that ACOs have adequate time to phase in their own care processes and infrastructure before they are held accountable for performance and that CMS has adequate data to set benchmarks for new measures before they transition to pay for performance according to the phase-in schedule in Table 81. In other words, the phase-in schedule indicated in Table 81 applies to a measure after it has been pay-for-reporting for the first two reporting periods it is in use. In this case, the new measures we are finalizing will be pay-for-reporting for the 2015 and 2016 reporting periods, which will take precedence over the phase-in schedule for ACOs that are currently participating in the Shared Savings Program. Using new measures as pay-for-reporting for the first two reporting periods they are in use will provide adequate time and data necessary to set the benchmarks for the 2017 reporting period when the measures will transition to pay for performance under the phase in schedule indicated in Table 81.

For example, assume a new measure is scheduled to phase in with reporting in PY1, reporting in PY2, and performance in PY3. Further assume that an ACO with a 2014 start date will be in its second performance year (PY2) when the measure becomes effective. In this example, according to the performance year phase-in schedule, the ACO would be responsible for complete and accurate reporting of the new measure in PY2 and for performance on the measure in PY3. However, because the measure is new and will be pay-for-reporting for the 2015 and 2016 reporting periods, this overrides the phase-in schedule because we would not have benchmark information for this ACO's PY3. In this example, if the ACO renews its participation agreement for a new agreement period then the ACO would be responsible for performance on the measure in PY1 of its new agreement period, because the measure was scheduled to be pay-for-performance in PY3 of the previous agreement period. If we change the assumptions in the example to an ACO with a start date of 2015, under the phase-in schedule the

ACO would be responsible for performance in PY3 which corresponds with the 2017 reporting period, the first year in which the measure is available to be used for pay-for-performance. In other words, each new measure is pay-for-reporting until it is possible to use it as pay-for-performance, and whether the ACO is subject to pay-for-performance at that time is determined by the phase-in schedule in Table 81.

We are also revising §425.502(a)(4) to provide that the quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure.

h. Aligning with PQRS sampling methodology

Proposal: As noted in the November 2011 Shared Savings Program final rule (76 FR 67900), the Shared Savings Program uses the same sampling method used by PQRS GPRO. Specifically, the sample for the ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, assigned beneficiaries is less than 411, the ACO must report on 100 percent, or all, of the assigned beneficiaries sampled. In the proposed rule, we stated that to the extent that PQRS modifies and finalizes changes in the reporting requirements for group practices reporting via the GPRO web interface, we proposed to make similar modifications to ACO reporting through the GPRO web interface. Specifically, as discussed in section III.K. of this final rule with comment period, we proposed to reduce the GPRO web interface minimum reporting requirements for PQRS reporting from 411 to 248 consecutively ranked and assigned patients for each measure or 100 percent of the sample for each measure if there are less than 248 patients in a given sample. We proposed that the reduced sample for each measure for reporting through the GPRO web interface would also apply to

ACOs. We stated that we believe that a reduction in the number of sampled beneficiaries would reduce reporting burden for ACOs while maintaining high statistical validity and reliability in results.

Comment: We received relatively few comments on this proposal, but most of those that commented supported the proposal. A majority of commenters also supported the PQRS proposal to reduce the reported sample size for groups of 100 or more EPs, and agreed that this smaller sample size would reduce reporting burden (please refer to section III.K.). However, a few commenters were concerned that a sample size of 248 may not adequately or accurately represent the diversity of an ACO's providers and suppliers, especially for larger ACOs. These ACOs can include mixed models of employed and independent-affiliated provider practices. Therefore, these commenters support reducing the sample size requirement only for smaller ACOs, such as those ACOs with 5,000 to 10,000 assigned beneficiaries. Alternatively, these commenters request that ACOs be given the option to continue to report a larger sample size if they prefer. A commenter also asked that CMS publish results that support the statistical validity and reliability of the proposed reduction of the sample from 411 to 248.

Response: Specific responses to comments on this proposal can be found in section III.K.4.a. of this final rule with comment period. We appreciate the comments from stakeholders that support the proposal to reduce the sample size and agree that this change will reduce reporting burden for ACOs. Moreover, commenters agreed that a reduction in the sample size to 248 would continue to be statistically valid and reliable. As discussed in section III.K.4.a, our internal assessments performed for PQRS confirm this conclusion. Additionally, we clarify that the GPRO web interface tool will continue to contain an oversample of 616 patients at it has previously, however, the number required for reporting is being reduced from 411 to 248. Because we have concluded that a sample of 248 is statistically valid and reliable, we disagree

that the reduced sample size will not adequately represent the diversity of the ACO's providers and suppliers. Further, we do not have a mechanism that would allow us to deviate from the established methodology used by the GPRO web interface, and therefore cannot offer an option at this time for ACOs to choose to be assessed on more than 248 patients. As noted above, the tool oversamples up to 616 patients, and ACOs may choose, but are not required, to report on all 616. We oversample to allow ACOs to include beneficiaries for quality reporting to replace beneficiaries ACOs are unable to report on, due to exclusions, so they can complete the minimum required number of patients. However, in accordance with the methodology previously adopted under PQRS, the ACO would only be assessed based on reporting for 248 patients using the existing sampling methodology that otherwise has been previously established.

In order to align with the policy being finalized for PQRS, we are reducing the required number of consecutively ranked patients reported for each measure module through the CMS web interface from 411 to 248. Because ACOs report using the same web interface tool used by PQRS, this reduction in the required sample size for reporting will reduce burden, while ensuring statistical validity and reliability is maintained. It also ensures consistency and equal treatment for all groups reporting through the GPRO web interface.

3. Request for Comments for Future Quality Measures

In the proposed rule (79 FR 40483), we indicated that in addition to the changes to the current set of measures for the Shared Savings Program discussed above, we were interested in public comment on additional measures that we may consider in future rulemaking. We particularly welcomed comments regarding the following issues:

- Gaps in measures and additional specific measures: We solicited comments on specific measures or measure groups that may be considered in future rulemaking to fill in gaps that may exist for assessing ACO quality performance.

- Caregiver experience of care: We solicited comment on additional specific caregiver experience of care measures that might be considered in future rulemaking.

- Alignment with Value-Based Payment Modifier (VM) measures: We solicited comment on whether there are synergies that can be created by aligning the ACO quality measure set with the measures used under the VM. Although we did not propose any changes to align with the measures used under the VM, we did seek comment on whether the VM composites should be considered in the future as a replacement for the two ACO claims-based ambulatory sensitive conditions admissions (ASCA) measures.

- Specific measures to assess care in the frail elderly population: We welcomed comments with suggestions of new measures of the quality of care furnished to the frail elderly population that we may consider adopting in future rulemaking.

- Utilization: We welcomed comments on whether it is sufficient for utilization information to be included in the aggregate quarterly reports to ACOs or whether utilization measures should also be used to assess the ACO's quality performance as an added incentive to provide more efficient care. If commenters were interested in having utilization measures included in the quality performance standard, we welcomed specific comments on what utilization measures would be most appropriate for future consideration and suggestions for how to risk adjust these measures.

- Health outcomes: We welcomed suggestions as to whether and when it would be appropriate to include a self-reported health and functional status measure in the quality performance standard. We specifically welcomed comments on the appropriateness of using a tool such the Health Outcomes Survey for health plans which assesses changes in the physical and mental health of individual beneficiaries over time. We also welcomed suggestions for alternatives to self-reported measures that may be considered in the future.

- Measures for retirement: We solicited input from commenters on any measures that should be considered for retirement in future rulemaking. We welcomed comments on whether to continue to require 'topped out" measures be included as pay for reporting measures. In addition, we noted that we were proposing changes to the benchmarking methodology for topped out measures.

- Additional public health measures: In the proposed rule, we noted that we may propose to include an additional preventive health measure in the quality measure set under the Shared Savings Program in future rulemaking. Specifically, we indicated that we were considering adding "Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling" (NQF #2152). This measure would reflect screening of Medicare beneficiaries covered under the existing Medicare benefit referred to as the "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse" benefit. We welcomed comments on the potential addition of this measure and noted that we would consider any comments received in developing any future proposal with respect to this measure.

Comment: Commenters identified a wide variety of specific measure gap areas that we should address, such as COPD, care coordination, medication management and adherence, preventive care/adult immunizations, pain, malnutrition, wounds, bladder control, outcome measures and cost/efficiency/utilization related measures. Some commenters provided suggestions for specific measures that we should consider in future rulemaking while other commenters provided more general suggestions about the types of additional measures that we should consider. For example, some commenters suggested that quality measures should be primarily designed to protect beneficiaries from inappropriate reductions in services by ACOs. Other commenters noted that to improve care for beneficiaries, the measures should focus on areas where: (a) CMS believes Medicare beneficiaries are receiving poor care today; and (b) it is

feasible for an ACO to make changes in care that would improve care in those areas using the limited resources available in the Shared Savings Program. Others opposed utilization measures, believing these types of measures are not necessary within the Shared Savings Program because of the inherent incentive for ACOs participating in the program to reduce unnecessary services and achieve savings. A commenter supported adding public health measures "…to help overcome the difficulties inherent in procedure-based measures that capture limited volumes of experience in rural settings." This commenter provided additional suggestions, such as that we exercise caution in interpreting results from self-reported measures, because of a tendency of rural respondents to understate the true burden of chronic illness and travel. Another commenter emphasized that measure development should not entirely focus on outcomes measures because process measures can also improve outcomes. Some measures without clear clinical evidence (that is, lacking NQF endorsement) should be avoided. Furthermore, survey measures should be minimal (and not heavily weighted) due to subjectivity, cost of collection, and risk of inaccurate representation based on response rate. This commenter also recommended that the number of measures required to be reported should be realistic and CMS should move toward the use of composites and outcome measures. Refining the measurement strategy in this way over time will allow for ACOs to mature in function, which takes a few years, and CMS should structure measure selection and performance measurement to reflect growth from fledgling ACO to a mature ACO. CMS should set up data reporting to be automated as much as possible. Finally, a commenter suggested that complementing the measurement strategy should be a forum for communication among ACO participants to share best practices and lessons learned. Comments regarding "topped out" measures for retirement are included in the discussion below regarding the adjustment of the benchmarks for "topped out" measures.

Response: We appreciate receiving the many thoughtful suggestions. We will consider

these suggestions further as we develop any future proposals for additional measures for the Shared Savings Program, which we would implement through rulemaking.

4. Electronic Reporting of Quality Measure Data

We believe that certified EHR technology used in a meaningful way is one piece of a broader health information technology infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. Through our programs such as the Medicare and Medicaid EHR Incentive Programs and the Stage 2 meaningful use (MU) requirements we seek to expand the meaningful use of certified EHR technology (CEHRT). Adoption of CEHRT by ACO participants and ACO providers/suppliers may help support efforts to achieve improvements in patient care and quality, including reductions in medical errors, increased access to and availability of records and data, improved clinical decision support, and the convenience of electronic prescribing. Additionally, we believe that the potential for the Shared Savings Program to achieve its goals could be further advanced by direct EHR-based quality data reporting by ACOs and their ACO participants and ACO providers/suppliers. This could help reinforce the use of CEHRT, reduce errors in quality measure submission, and achieve data submission efficiencies. We believe ACOs and their providers should be leaders in encouraging EHR adoption and should be using CEHRT to improve quality of care and patient safety and to reduce errors.

Furthermore, beginning in 2015, eligible professionals that do not successfully demonstrate meaningful use of CEHRT will be subject to a downward payment adjustment under Medicare that starts at -1 percent and increases each year that an eligible professional does not demonstrate meaningful use, to a maximum of -5 percent. A final rule establishing the requirements of Stage 2 of the Medicare EHR Incentive Program appeared in the September 4, 2012 **Federal Register** (Medicare and Medicaid Programs; Electronic Health Record Incentive

Program—Stage 2 Final Rule) (77 FR 53968). Included in this final rule are the meaningful use and other requirements that apply for the payment adjustments under Medicare for covered professional services provided by eligible professionals failing to demonstrate meaningful use of CEHRT, including the CQM reporting component of meaningful use. As previously discussed in section III.M.2, we are finalizing a proposal to revise the name and the specifications for the quality measure regarding EHR adoption to take the changing incentives into account. Specifically, we are changing the name of ACO #11 from "Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment" to "Percent of PCPs Who Successfully Meet Meaningful Use Requirements" to more accurately reflect what is being measured.

Additionally, under a group reporting option established for the Medicare EHR Incentive Program (77 FR 54076 through 54078), EPs participating in an ACO under the Shared Savings Program who extract the data necessary for the ACO to satisfy the quality reporting requirements of the Shared Savings Program from CEHRT would satisfy the CQM reporting component of meaningful use as a group for the Medicare EHR Incentive Program. In addition to submitting CQMs as part of an ACO, EPs have to individually satisfy the other objectives and associated measures for their respective stage of meaningful use.

However, we clarified that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all of its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO web interface measures and satisfy the reporting requirements under the Shared Savings Program in order to its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although these group reporting requirements were established under the Medicare EHR Incentive Program, the Shared Savings Program regulations were not amended to reflect these reporting requirements. Therefore, we proposed to amend the regulations governing the Shared Savings Program to align with the requirements previously adopted under the Medicare EHR Incentive Program in order to provide that EPs participating in an ACO under the Shared Savings Program can satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the ACO reports GPRO web interface measures by adding new paragraph (d) to §425.506. We proposed that this new paragraph would provide that EPs participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when: (1) the eligible professional extracts data necessary for the ACO to satisfy its quality reporting requirements from CEHRT; and (2) the ACO satisfactorily reports the ACO GPRO measures through a CMS web interface.

Although we did not propose any new requirements regarding EHR based reporting under the Shared Savings Program, we welcomed suggestions and comments about issues which we would consider in developing any future proposals. We especially solicited comment on the feasibility of an ACO to be a convener and submitter of quality measures through an EHR or alternative method of electronically reporting quality measures to us. We indicated our interest in the opportunities and barriers to ACO EHR quality measure reporting, as well as ways to overcome any barriers. We also welcomed suggestions on alternative ways that we might implement EHR-based reporting of quality measures in the Shared Savings Program, such as directly from EHRs or via data submission vendors. We solicited comment on whether EHR reporting should be a requirement for all Shared Savings Program ACOs or if the requirement for EHR reporting should be phased in gradually, for instance through a separate risk track or by

the establishment of a "core and menu" quality measure set approach in which we would establish a core set of required quality measures and then supplement these required measures with a menu of additional measures (such as EHR-based reporting) from which an ACO could choose. This approach could provide ACOs with additional flexibility and allow them to report on quality measures that better reflect any special services they provide. As an alternative, we also solicited comment on whether ACO providers/suppliers could use a local registry-like version of the GPRO web interface to capture relevant clinical information and to monitor performance on all Medicare patients throughout the year and to more easily report quality data to CMS annually.

Comment: We received a wide variety of suggestions from ACOs and other stakeholders. Most ACOs support CMS's decision not to propose any new requirements at this time regarding EHR based reporting, and they agree with aligning the Shared Savings Program with the EHR Incentive Program whereby EPs participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its quality reporting requirements using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface. Some commenters believe the technical and operational barriers outlined in the proposed rule were severely understated. Healthcare Information and Management Systems Society (HIMSS) considered requiring EHR-based reporting of quality measures in the Shared Savings Program to be premature. Commenters raised concerns that the current lack of interoperability capabilities for ACOs that are formed by disparate organizations, often hospitals and physician groups coming together, but using differing EHR platforms that do not communicate electronic data sufficiently to centralize data for quality reporting would limit the ability of ACOs to successfully report quality through an EHR. They state it will take significant resources and time to ensure that interoperability is

achieved. Rather than requiring EHR-based reporting, some commenters suggested that CMS should give providers the option to report through EHRs.

Response: We appreciate the comments recommending that we not establish any new requirements at this time regarding EHR based reporting under the Shared Savings Program. We also appreciate the comments supporting aligning the Shared Savings Program with the EHR Incentive Program whereby EP participating in an ACO can satisfy the CQM reporting component of meaningful use when the EP extracts data necessary for the ACO to satisfy its GPRO reporting requirement using a CEHRT and the ACO satisfactorily reports the GPRO measures through the CMS web interface.

We will continue to work toward electronic reporting of quality measures, keeping in mind the unique relationship ACOs have with their ACO participants and ACO providers/suppliers. We understand and appreciate the feedback from those stakeholders who raised important concerns about the readiness of ACOs and EHR systems to report quality electronically under the Shared Savings Program. We will use the information provided by commenters to work with ACOs and other stakeholders to develop possible ways to encourage EHR adoption taking into account input from ACOs on challenges for ACO electronic collection and submission of measures. In addition, we will consider the input we have received from stakeholders when deciding what additional requirements should be proposed in future rulemaking to encourage EHR adoption and use by ACOs and their ACO participants and ACO providers/suppliers.

After consideration of the comments received regarding this proposal, we are finalizing our proposal to codify in the Shared Savings Program rules for 2015 and beyond that an eligible professional that is an ACO provider/supplier can satisfy the CQM reporting component of meaningful use when the eligible professional extracts data from CEHRT necessary for the ACO

to satisfy its quality reporting requirements under the Shared Savings Program and the ACO reports the GPRO measures through the CMS web interface. This policy will be codified at § 425.506(d) of the Shared Savings Program regulations. We emphasize that if an EP intends to use this group reporting option to meet the CQM reporting component of meaningful use, then the EP would have to extract all its CQM data from a CEHRT and report it to the ACO (in a form and manner specified by the ACO) in order for the EP to potentially qualify for the Medicare EHR Incentive Program. The ACO must also report the GPRO measures through the CMS web interface in order for its EPs to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program.

Although this amendment to the regulations will align the Medicare Shared Savings Program regulations with the existing requirements under the Medicare EHR Incentive Program, we intend to take steps in the future to better align and integrate EHR use into quality reporting under the Shared Savings Program.

5. Quality Performance Benchmarks

a. Overview of Current Requirements

Section 1899(b)(3)(C) of the Act directs 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 purposes of assessing such quality of care." Under the current Shared Savings Program regulations at §425.502, the following requirements with regard to establishing a quality performance benchmark for measures apply: (1) during the first performance year of an ACO's agreement period, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on certain measures (see Table 1

of the November 2011 Shared Savings Program final rule (76 FR 67889 through 67890), for details of the transition for each of the 33 measures); (3) we designate a quality performance benchmark and minimum attainment level for each measure, and establish a point scale for the level of achievement on each measure; and (4) we define quality performance benchmarks using FFS Medicare data or using flat percentages when the 60th percentile is equal to or greater than 80.00 percent.

Section 425.502(b)(2) governs the data that CMS uses to establish the quality performance benchmarks for quality performance measures under the Shared Savings Program. Consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time, §425.500(b)(3) states that in establishing the measures to assess the quality of care furnished by an ACO, CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

Subsequently, we discussed several issues related to the establishment of quality performance benchmarks in the CY 2014 PFS final rule with comment period (78 FR 74759 through 74764). In that rule (78 FR 74760), we finalized a proposal to combine all available Medicare FFS quality data, including data gathered under PQRS (through both the GPRO web interface tool and other quality reporting mechanisms) and other relevant FFS quality data reported to CMS (including data submitted by Shared Savings Program and Pioneer ACOs) to set the quality performance benchmarks for 2014 and subsequent reporting periods. In establishing this policy, we determined that it was appropriate to use all FFS data rather than only ACO data, at least in the early years of the program, to avoid the possibility of punishing high performers where performance is generally high among all ACOs. We did not finalize a proposal to use Medicare Advantage (MA) data alone or in combination with FFS data in the

short-term. Instead, we stated in the CY 2014 PFS final rule with comment period (78 FR 74760) that we intended to revisit the policy of using MA data in future rulemaking when we have more experience setting benchmarks for ACOs.

Additionally, in the CY 2014 PFS final rule with comment period, we retained the ability to use flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure, so that ACOs with high performance on a measure are not penalized (78 FR 74760). More specifically, we will now use all available FFS data to calculate benchmarks, including ACO data, except where performance at the 60th percentile is equal to or greater than 80 percent for individual measures. In these cases, a flat percentage will be used to set the benchmark for the measure. This policy allows ACOs with high scores to earn maximum or near maximum quality points while still allowing room for improvement and rewarding that improvement in subsequent years.

As previously discussed, the first performance year of an ACO's agreement period is pay for reporting only, so ACOs earn their maximum sharing rate for completely and accurately reporting all 33 quality measures. Quality performance benchmarks are released in subregulatory guidance prior to the start of the quality reporting period for which they apply so that as we phase in measures to pay for performance, ACOs are aware of the actual performance rates they will need to achieve to earn the maximum quality points under each domain. In the November 2011 Shared Savings Program final rule, we indicated our intent to gradually raise the minimum attainment level to continue to incentivize quality improvement over time and noted that we would do so through future rulemaking after providing sufficient advance notice with a comment period to allow for industry input (76 FR 67898). In the CY 2014 PFS final rule with comment period, we reiterated our policy of setting quality performance benchmarks prior to the reporting year for which they would apply (78 FR 74759). Specifically, we use data submitted in

2013 for the 2012 reporting period to set the quality performance benchmarks for the 2014 reporting period. However, we recognize that in the first few years of the Shared Savings Program, we will only have a limited amount of data for some measures, which may cause the benchmarks for these measures to fluctuate, possibly making it difficult for ACOs to improve upon their previous year's performance. Stakeholders have also told us that they prefer to have a stable benchmark target so that they can be rewarded for quality improvement from one year to the next. Therefore, instead of modifying quality performance benchmarks annually, in the CY 2014 PFS final rule with comment period (78 FR 74761) we stated that we would set the benchmarks for the 2014 reporting year in advance using data submitted during 2013 for the 2012 reporting year, and continue to use that benchmark for 2 reporting years (specifically, the 2014 and 2015 reporting years). We further indicated our intention to revisit this issue in future rulemaking to allow for public comment on the appropriate number of years that a benchmark should apply before it is updated.

b. Revisions for Benchmarking Measures That Are "Topped Out"

In the discussion of measures in the CY 2015 Physician Fee Schedule proposed rule, we indicated that some measures may be topped out, meaning that all but a very few organizations achieve near perfect performance on the measure. Since publication of the quality performance benchmarks for the 2014 and 2015 quality reporting years, a number of ACOs have noted that using available national FFS data has resulted in some benchmarks where the 80th or 90th percentiles approach 100 percent performance on the measure. Stakeholders have suggested it is unreasonable to hold organizations, especially very large organizations such as ACOs to this high standard and that it may be easier for smaller and medium size physician practices to achieve higher levels of performance given their smaller patient populations. We believe these concerns have merit because we have looked at the FFS data submitted to CMS and agree it is

possible that smaller practices or practices with smaller populations may be able to achieve these higher levels of performance more easily than larger practices or organizations with larger patient populations. Therefore, we proposed certain modifications to our benchmarking methodology to address the way that such "topped out" measures are treated for purposes of evaluating an ACO's performance. Specifically, when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent, we would use flat percentages for the measure, similar to our policy under §425.502(b)(2)(ii) of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We believe this approach would address concerns about how topped out measures affect the quality performance standard while continuing to reward high performance, and being readily understandable to all. We proposed to revise §425.502(b)(2)(ii) to reflect this policy. We invited comments on this proposal. We also invited comments on other potential approaches for addressing topped out measures. We indicated that we would use any comments received to help develop any future proposals regarding topped out measures. For example, we welcomed comments on whether we should drop topped out measures from the measures set, fold them into composites, or retain them but make them pay for reporting only.

Comment: Commenters were generally in agreement with our proposal to use flat percentages for topped out measures, which is consistent with our policy of using flat percentages when the 60th percentile is greater than 80 percent to address clustered measures. We received a wide variety of responses to our request for comment on what should be done with topped out measures through future rulemaking. Many commenters supported retaining such measures with the view that quality measures are intended to protect Medicare beneficiaries from receiving inappropriate care. If all but a few organizations achieve near perfect performance, the commenters believe it would be important to retain that measure to encourage

better performance from the low performing organizations, and to prevent backsliding by the high performers. Other commenters, including MedPAC, suggested removing topped out measures to reduce reporting burden. Others suggested that topped out measures could be dropped or moved from being process-based to clinical outcome-based and be folded into composites to prevent "back sliding," or that they could be considered "deemed met" without a reporting requirement but available for audit if so chosen.

Response: We appreciate the commenters' support for the proposal to use flat percentages when the national FFS data results in the 90th percentile performing at greater than or equal to 95 percent. We also appreciate the additional suggestions regarding treatment of topped out measures and intend to consider this issue further in future rulemaking.

Final Decision: After consideration of the comments received on this issue, we are finalizing our proposal to use flat percentages when the national FFS data results in the 90th percentile for a measure are greater than or equal to 95 percent. We are also finalizing our proposed revisions to §425.502(b)(2)(ii) to reflect this policy. Although this final policy is similar to our current policy for setting benchmarks based on flat percentages when the 60th percentile is equal to or greater than 80.00 percent, we clarify that this methodology would apply to all measures, including measures whose performance rates are calculated as ratios, for example, measures such as the ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe it is appropriate to apply this methodology to all topped out measures, including measures whose performance rates are calculated as ratios. Measures calculated and reported as ratios may also become topped out and we believe it is important to keep a consistent approach for addressing all Shared Savings Program measures that become topped out.

c. Quality Performance Standard for Measures that Apply to ACOs that Enter a Second or Subsequent Participation Agreement

As discussed previously, during an ACO's first participation agreement period, the quality performance standard during the first performance year is initially set at the level of complete and accurate reporting, and then, during performance years 2 and 3 within the ACO's first agreement period, the quality performance standard is phased in such that the ACO is assessed on its performance on selected measures. We did not directly indicate the quality performance standard that would apply if an ACO were to subsequently enter into a second or subsequent participation agreement. However, §425.502(a)(1) provides that during the first performance year of an ACO's agreement period, CMS will define the quality performance standard at the level of complete and accurate reporting of all quality measures. As drafted, this regulation could be read to imply that the quality performance standard for ACOs in the first performance year of a subsequent agreement period would also be set at the standard of full and accurate reporting. We do not believe it is appropriate for an ACO in a second or subsequent agreement period to report quality measures on a pay-for-reporting basis if they have previously reported these measures in a prior agreement period. The ACO would have gained experience reporting the quality measures during the earlier agreement period, and as a result, we do not believe it would be necessary to provide any further transition period. Rather, we believe it would be appropriate to assess the ACO's actual performance on measures that have been designated as pay for performance during all 3 years of the second or subsequent participation agreement period.

Accordingly, we proposed to revise our regulations to expressly provide that during a second or subsequent participation agreement period, the ACO would continue to be assessed on its performance on each measure that has been designated as pay for performance. That is, the

ACO would continue to be assessed on the quality performance standard that would otherwise apply to an ACO if it were in the third performance year of the first agreement period. We will do this by modifying §425.502(a)(1) and (a)(2) to indicate that the performance standard will be set at the level of complete and accurate reporting of all quality measures only for the first performance year of an ACO's first agreement period, and that during subsequent agreement periods, pay for performance will apply for all three performance years.

Comment: We received relatively few comments on this proposal. A number of those that responded supported the proposal. A few were hesitant to support it, suggesting that a performance standard for a quality measure should not be continued into a second or a subsequent participation agreement period if there have been any significant changes in the measure set and/or in the specifications used to calculate performance on the measures. In such cases, those measures that have changed should follow the same schedule as would apply to an ACO in its first agreement period. Another example of a concern these commenters raised is if an ACO with a 2013 start date (three year agreement for 2013 through 2015) chooses to sign a subsequent three year agreement (for 2016 through 2018), that requires it to accept risk, then the ACO would possibly be facing new benchmarks beginning in PY 2016 and would not be afforded a one year pay for reporting transition period to gain experience with the new benchmarks.

Response: We appreciate the comments in support of this proposal. We believe that concerns that were expressed by some commenters about changes in the measure set are addressed through the phase-in schedule for new measures, as outlined in Table 81, and our policy, finalized above, that all new measures will be pay-for-reporting for all ACOs for the first two reporting periods in which they are in use, regardless of the phase-in schedule. This will permit time for CMS to gather data for benchmarking and publish benchmarks prior to the start

of the third reporting period in which a new measure is in use. This two year grace period will also permit ACOs to become accustomed to the measure before it becomes pay-for-performance. So in the example given by the commenter, the ACO with a 2013 start date would not be subject to pay-for-performance in its first year of the subsequent agreement period (starting in 2016) for any of the new measures finalized in this rule. The first opportunity for the new measures to be used as pay-for-performance would be for the 2017 reporting period, which would correspond to this ACO's second performance year of its subsequent agreement period. Because the ACO would be in its subsequent agreement period, all measures would be pay-for-performance at that time, with the exception of measures that remain pay-for-reporting in all years, according to the phase-in schedule indicated in Table 81. For example, the Depression Remission at 12 Months measure (ACO# 40) is pay-for-reporting for all three years of an ACO's first agreement period. In a subsequent agreement period, ACOs will continue to be assessed on this measure as pay-for-reporting, which corresponds to the level of performance required in PY3 of the first agreement period.

Final Decision: We are finalizing our proposal to modify §425.502(a) to indicate that for ACOs in a second or subsequent agreement period, all measures will be pay for performance for all three performance years unless the measure is designated as pay-for-reporting for all three years, as indicated in Table 81. We clarify that, as discussed in more detail above, this policy applies only to measures that have been in use for two years or more, for which benchmarks are available, and thus, would not apply to new measures, which are designated as pay-for-reporting during the first two reporting periods they are in use.

d. Timing for Updating Benchmarks

As discussed in the CY 2014 PFS final rule with comment (78 FR 74761), we have further considered suggestions from ACOs regarding the appropriate number of years that a

benchmark should apply before it is updated. ACOs suggested that there be a longer period of time to gain experience with the performance measure, before the benchmark is further updated. ACOs also indicated that it would be desirable to set and leave benchmarks static for additional performance years so that they have a quality improvement target to strive for that does not change frequently. ACOs believe that a stable benchmark would enhance their ability to be rewarded for quality improvement, as well as quality achievement, from one year to the next. We recognize, however, that there could be some concerns about lengthening the period between updates to the quality performance benchmarks. The current benchmarks as discussed previously, for example, are based on a combination of all available Medicare FFS quality data, including data gathered under PQRS, the Shared Savings Program and Pioneer ACO Model, but not MA quality data. To the extent that the benchmarks are based on quality data reported by a large number of ACOs and other FFS entities, we believe it is reasonable to use them to assess the quality performance of ACOs. Furthermore, as discussed in the 2014 PFS final rule with comment period (78 FR 74761), we are also persuaded that we should establish a longer period between updates to the benchmarks in order to provide ACOs with a more stable target for measuring quality improvement. In the absence of this stability, it could be very difficult to assess quality improvement from year to year.

In the 2014 PFS final rule with comment period, we noted that we intended to address the number of years between updates to the benchmarks again in future rulemaking in order to allow for public comment. Therefore, we considered how long benchmarks should be in place before they are updated. We considered a range of options, from setting benchmarks every 2 years to setting benchmarks every 5 years. For example, we considered the option of setting benchmarks every 3 years. However, we note that ACO agreement periods are 3 years long and a new cohort of ACOs enters the program each year. As a result, setting benchmarks every 3 years might

advantage some ACOs over others, particularly ACOs that have an agreement period during which benchmarks are not updated. Therefore, we proposed to update benchmarks every 2 years. We believe 2 years is an appropriate amount of time because the Shared Savings Program is relatively new and we do not have extensive experience in setting benchmarks under the Shared Savings Program. Updating the benchmarks every 2 years would enable us to be more flexible and give us the ability to make adjustments more frequently if appropriate. We note, however, that we may revisit this policy as more ACOs enter the program, more FFS data is collected which could help us better understand to what extent benchmarks should vary from year to year, or if we make any future proposals regarding the use of MA quality data for setting benchmarks.

Accordingly, we proposed to revise §425.502(b) to add a new paragraph (b)(4)(i), which would provide that CMS will update benchmarks every 2 years. To illustrate this proposed policy, the existing quality performance benchmarks, which are based on data submitted in 2013 for the 2012 reporting period would apply for a total of 2 performance years (the 2014 and 2015 performance years) after which we would reset the benchmarks for all ACOs based on data for the 2014 reporting period that is reported during 2015. These updated benchmarks would apply for the 2016 and 2017 performance years. This timeline is summarized in Table 85. Under this proposal, ACOs would have a stable target for quality achievement for 2 years, which should improve the opportunity for ACOs to be rewarded for improvement from year to year compared to that benchmark. We also proposed to revise §425.502(b) to add a new paragraph (b)(4)(ii), which would provide that for measures introduced in the first year of the 2-year benchmarking cycle, the benchmark will be established in the second year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

We solicited comment on this proposal. We specifically solicited comment on the appropriate number of years that a benchmark should remain stable before it is updated. We also welcomed comments about when annual updates might be appropriate such as when there is a substantive specification change to a measure between years. For instance, the age range used for the breast cancer screening measure is different in 2014 than in 2013, or when the measure owner modifies or retires a measure. Additionally, although we proposed to retain our current policy of using the most recent available data to set the quality performance benchmarks, we also solicited comment on whether data from other reporting periods should also be considered in establishing benchmarks that will apply for 2 performance years. Specifically, we sought input on whether data from multiple years should be used to help provide more stable benchmarks. For example, should data submitted for the 2013 and 2014 reporting periods be combined to set benchmarks for the 2016 and 2017 performance years?

Comment: We received a wide range of comments in response to this proposal. In general most commenters supported setting benchmarks for at least two years but many, including some ACOs, supported a longer period of at least three years to align with the Shared Savings Program agreement period to provide more stability for ACOs. There were some commenters that suggested more frequent adjustment of benchmarks under certain situations, suggesting that more frequent benchmark updates may be necessary whenever there are substantive specification changes for a measure, such as changes in the dominator or frequency. For example, a commenter stated that even slight modifications to a measure specification could eliminate any opportunity to establish a valid benchmark and that CMS must therefore consider establishing new benchmarks when even “non-substantive” changes are made to measure. A commenter suggested that instead of the proposed two year interval, benchmarks should be adjusted annually if there is a statistically significant performance change across all

organizations. Some commenters suggested the use of multiple years of data to set benchmarks, suggesting, for example, that some measures could be susceptible to year specific events that could skew results.

Response: We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable quality improvement targets. We believe that setting benchmarks for two years provides ACOs with stable quality improvement targets while not advantaging some ACOs over others by setting them for three years. We also agree with commenters who suggested the use of multiple years of data to set benchmarks to reduce the effect that year to year variation might have on the benchmarks. Therefore, we will use up to 3 years of FFS data to set benchmarks, if available. This should provide sufficient stability to minimize year to year variation while also representing reasonably current practices, if the data is available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years.

We are finalizing our proposal to set benchmarks for two years to provide ACOs with stable targets for quality improvement. In addition, we will use up to three years of FFS data to set benchmarks, if available. The use of multiple years of FFS data to set benchmarks will apply to all newly established benchmarks, but will not affect existing benchmarks, which apply to the 2014 and 2015 performance years. We are finalizing our proposal to revise §425.502(b) to add a new paragraph (b)(4)(i) providing that CMS will update benchmarks every 2 years. In light of our decision to set the quality performance standard for a newly introduced measure at the level of complete and accurate reporting for the first two reporting periods for which the measure is in use, we are revising proposed §425.502(b)(4)(ii) to provide that for newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established in that year and updated along with the other measures at the start

of the next 2-year benchmarking cycle. For example, if a new measure is scheduled to become pay for performance in 2017 after being used for pay-for-reporting for 2015 and 2016, it will be set for the 2017 performance year and subsequently reset at the beginning of the next 2-year benchmarking cycle (2018-2019). In other words, such a measure would have its benchmark set for a single year before phasing into the biennial benchmarking schedule outlined in Table 84.

TABLE 84: Timeline for Setting and Updating Quality Performance Benchmarks

Reporting period for data used to set benchmark	Year data is analyzed, and benchmark is published	Performance year and reporting period to which benchmark applies
2012	2013	2014 & 2015
2012, 2013, 2014	2015	2016 & 2017
2014, 2015, 2016	2017	2018 & 2019

6. Rewarding Quality Improvement

a. Current Approach to Rewarding ACOs for Both Quality Attainment and Quality Improvement

ACOs must meet a CMS-specified quality performance standard in order to be eligible to share in savings. The Shared Savings Program quality performance standard currently consists of a set of quality measures spanning four domains that are collected via the patient and caregiver experience of care survey, calculated by CMS from internal administrative and claims data, and submitted by the ACO through the CMS web interface. The four domains include patient/caregiver experience of care, care coordination/patient safety, preventive health, and at-risk populations. The measures collected through the CMS web interface are also used to determine whether eligible professionals that bill through the TIN of an ACO participant qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment. Eligible professionals that bill through the TIN of an ACO participant may qualify for the PQRS incentive payment or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO quality measures on their behalf.

Under current policy, the quality performance standard is defined at the level of full and complete reporting for the first performance year of an ACO's agreement period. After that, an ACO must meet certain thresholds of performance and is rewarded on a sliding scale in which higher levels of quality performance translate to higher rates of shared savings. This scale, therefore, rewards improvement over time, since higher performance translates to higher shared savings. For example, an ACO that performs at the 80th percentile one year and then at the 90th percentile the next year would receive a higher level of shared savings in its second year than its first year, based on its improved quality performance. In this way, ACOs are rewarded for both attainment and improvement. This is particularly true when benchmarks are stable for more than one year, as discussed earlier in this section.

We recognize that rewards for both quality attainment, as well as quality improvement are not always built in to pay-for-performance initiatives. For example, in HVBP (Hospital Value-Based Purchasing) hospitals are scored based on the higher of their achievement or improvement on specified quality measures, with some hospitals receiving incentive payments if their overall performance is high enough relative to their peers. In the November 2011 final rule establishing the Shared Savings Program (76 FR 67897), we indicated in response to comments that we believe the approach of offering more points for better quality performance also offers an implicit incentive for continuous quality improvements, since it incorporates a sliding scale in which higher levels of quality performance translate to higher sharing rates. We believed that high performing ACOs should do well under this approach since it recognizes and provides incentives for ACOs to maintain high quality performance in order to maximize their share of savings and minimize their share of losses.

b. Additional Rewards for Quality Improvement

ACOs and other stakeholders have suggested that the current quality points scale described above does not adequately reward ACOs for both quality attainment and improvement. They request that we further strengthen the incentives for quality improvement by including an additional explicit reward for those ACOs that improve from one year to the next.

As discussed previously, the existing quality performance standard includes a sliding point scale that rewards ACOs for certain levels of attainment. In addition, we note that under the final policy discussed above in which we will establish a stable quality performance benchmark for a period of 2 years, there should be an even greater opportunity for every ACO to demonstrate improvement and be rewarded for that improvement from year to year. However, we were persuaded by suggestions from stakeholders that an additional, more explicit reward should be included for ACOs that improve their quality scores from year to year. Therefore, we proposed to revise our existing quality scoring strategy to explicitly recognize and reward ACOs that make year-to-year improvements in their quality performance scores on individual measures.

To develop such an approach, we looked to the MA program, which has already successfully developed and implemented a formula for measuring quality improvement. The MA five star rating program computes an improvement change score which is defined as the score for a measure in a performance year minus the score in the previous performance year. The MA five star rating program then measures each plan's net quality improvement by calculating the total number of significantly improved quality measures and subtracting the total number of significantly declined quality measures. This is an approach that we believed was also appropriate for measuring quality improvement for ACOs. (For more details on the formula for calculating the MA quality improvement measure, see the discussion in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the

CMS website at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.)

We continue to believe it is important to recognize that the Shared Savings Program is not a managed care program. Unlike MA, this program's design retains FFS flexibility and the freedom of choice available to beneficiaries under Medicare Parts A and B which generally necessitates different program requirements. However, in this case we believe there would be significant advantages for the Shared Savings Program to adopt the formula for a quality improvement measure that MA has already developed and implemented rather than attempt to develop a new formula for a quality improvement measure. In particular, the MA measure formula has already been fully developed and vetted with stakeholders, in the context of the MA program, with detailed operational specifications and previously shared with the public.

In addition, we believe it is important to add a quality improvement measure to the Shared Savings Program in a manner that would minimize disruption for ACOs. We believe it would be undesirable for both ACOs and the program if the quality improvement measure were added in a way that required extensive revisions to the current quality measurement methodology, for example, reweighting of the four quality measure domains. Therefore, we proposed to add a quality improvement measure to award bonus points for quality improvement to each of the existing four quality measure domains. For each quality measure domain, we proposed to award an ACO up to two additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieved within each of the four domains. Under this proposal, the total possible points that could be achieved in a domain, including up to 2 bonus points, could not exceed the current maximum total points achievable within the domain.

ACOs would achieve bonus points for this quality improvement measure in a domain if they achieve statistically significant levels of quality improvement for measures within the domain, as discussed below. Otherwise, the current methodology for calculating the ACO's overall quality performance score would continue to apply (see §425.502(e) and 76 FR 67895 through 67900). Additional details about the proposal to incorporate bonus points into the quality performance scoring methodology are discussed in the CY 2015 Physician Fee Schedule proposed rule (79 FR 40490 through 40492). Highlights of the methodology we proposed are as follows.:

The quality improvement measure scoring for a domain would be based on the ACO's net improvement in quality for the other measures in the domain. The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

Improvement Change Score = score for a measure in performance year minus score in previous performance year.

In general, for a measure to be eligible to be included for purposes of determining quality improvement and awarding bonus points in a domain for a performance year, the measure must be a measure for which an ACO was scored in both the performance year and the immediately preceding performance year. Measures that were not scored in both the performance year and the immediately preceding performance year, for example, new measures, would not be included in the assessment of improvement. Otherwise, for purposes of determining quality improvement and awarding bonus points, we would include all of the individual measures within the domain, including both pay-for-reporting measures and pay-for-performance measures. In determining improvement, the actual performance score achieved by the ACO on the measure would be used, not the score used to determine shared savings. In other words, we would calculate a

performance score for each measure, regardless of whether it is pay for reporting or pay for performance, and include the score in the report we provide to the ACO. For example, all measures are pay for reporting in the first year of an ACO's first agreement period, but even though the ACO will receive full credit for all reported measures, its actual performance on those measures will also be scored and provided to the ACO for informational purposes. We believe it is appropriate to use these actual performance scores to assess improvement on a measure from year to year, regardless of whether the measure is designated as a pay for reporting or a pay for performance measure in that performance year because the performance scores achieved by the ACO provide the best indication of the actual change in quality performance by the ACO.

If the ACO is in its first performance year of its first agreement period, then it would not be possible, of course, to measure quality improvement. Therefore, for these ACOs the existing scoring methodology would continue to apply and no bonus points would be awarded. If an ACO in its second or subsequent performance year does not experience an improvement nor a decline in quality performance for any of the selected measures compared to its previous reporting period, or it experiences an improvement for some measures but has an equal or greater number of measures where quality performance has declined, then the ACO would likewise not be awarded any bonus points. If an ACO renews a participation agreement, then the measurement of quality improvement would be based on a comparison between performance in the first year of the new agreement period and performance in the 3rd year of the previous agreement period.

For each qualifying measure, we would determine whether there was a significant improvement or decline between the two performance years by applying a common standard statistical test. (See the discussion of the t-test for calculating the MA quality improvement measure in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80,

which can be downloaded from the CMS website at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html). Statistical significance testing in this case assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same. The test recognizes and appropriately adjusts measures at both high and low levels of performance for statistically significant levels of change. Under this methodology, we can be reasonably certain, at a 95 percent level of confidence, that statistically significant differences in an ACO's quality measure performance for a year compared to the previous year are real and not simply due to random variation in measure sampling.

The awarding of bonus points would be based on an ACO's net improvement within a domain, and would be calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures. Up to 2 bonus points would be awarded on a sliding scale based on the ACO's net improvement for the domain compared to the total number of individual measures in the domain.

Consistent with our current quality methodology, the total points earned for measures in each domain, including any quality improvement points, would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a final overall quality performance score and sharing rate for each ACO that will be used to determine the amount of shared savings or, if applicable the amount of losses it owes, consistent with the requirements under §425.502(e).

In developing this proposal to award bonus points for quality improvement, we considered several alternative options. Specifically, we considered whether it would be more appropriate not to award bonus points but instead to include a computed quality improvement

measure that would be incorporated into the current scoring methodology just as any other measure would be added. Under this alternative approach, we would increase the total possible points that could be awarded in a domain. However, we did not propose that approach because we believe that awarding bonus points would provide the desired incentive, would be more understandable and less disruptive, and would not require extensive changes to the quality performance standard. By awarding bonus points we also avoid the need to develop ways to avoid unfairly penalizing new ACOs. Similarly, ACOs that have already achieved a very high level of quality for an individual measure may not be able to achieve further statistically significant improvement for the measure. Such ACOs could otherwise be disadvantaged if they were not able to earn performance points for a new quality improvement measure added to the total measures in the domain. We believe our quality improvement proposal mitigates these concerns because the measure recognizes incremental improvement at higher levels of performance and does not impose any penalty on ACOs that have already achieved a high level of performance.

We also considered whether we should provide an even greater additional incentive by increasing the total possible bonus points, perhaps up to 4 points to provide a higher incentive for greater levels of quality improvement. However, we did not propose that option because we were concerned that awarding 4 points for the quality improvement measure could overweight the additional incentive for quality improvement given that the program already rewards higher performance with a greater share of any savings.

In addition, we had some concerns about whether it would be appropriate to use the "pay for reporting" data reported to us, given that this information does not affect an ACO's quality performance score in the first performance year. Therefore, we considered whether the quality improvement score should apply only to those ACOs that have completed at least two

performance years. Under this alternative approach, ACOs would have an opportunity to be assessed based on their actual quality measure performance before being assessed on their quality improvement scores. We did not select this approach because we wanted to provide an incentive that would apply as soon as possible in the agreement period. Furthermore, as noted earlier, we believe it would be appropriate to include pay-for-reporting measures for purposes of awarding bonus points since under §425.500(f) ACOs are required to report pay-for-reporting measures completely, accurately, and timely.

We proposed to add a new paragraph (e)(4) to §425.502 to incorporate this process for calculating bonus points for quality improvement into the quality performance scoring methodology. We solicited comments on this proposal and welcomed comments on the alternative approaches discussed in the proposed rule. We also solicited comments on whether there are other alternative approaches to explicitly rewarding quality improvement for ACOs, and whether the implicit reward for quality improvement provided under the current regulations is sufficient.

We also welcomed any suggestions on how the Shared Savings Program might integrate elements of other quality improvement methodologies such as those employed by HVBP or MA. Such comments would be considered in developing possible future proposals to further align with other Medicare quality improvement programs.

Comment: Commenters were supportive of explicitly recognizing and rewarding ACOs that make year to year improvements in the manner proposed. Many commenters, however, felt that our proposal did not go far enough and recommended instead that CMS award up to four bonus points (rather than two) for quality improvement in each of the existing four quality measure domains, or permit bonus points in one domain to influence the weighting of the domain. These commenters pointed out that the proposal to award up to two bonus points would

increase the overall quality performance score for an ACO by at most 14 percent. Some commenters suggested additional approaches, such as awarding an additional 10 percent of shared savings for those ACOs that score in the top 10 percent on quality measures. Another example is a suggestion that ACOs be allowed to retain 50% of their share of savings regardless of the MSR if their overall quality score improves year-over-year.

Response: We appreciate the overall support from commenters who generally agreed with the proposal to offer an additional and explicit reward for improving quality performance in the Shared Savings Program. This additional reward would complement and reinforce our current quality performance scoring system that implicitly takes into account improvements over prior performance and rewards ACOs with a greater share in savings for greater quality performance. We believe that adding an explicit incentive places even greater emphasis on quality improvement, encouraging all ACOs to continue to improve quality for their patient populations over time, in addition to maintaining existing high quality levels. The success of the Shared Savings Program is dependent in large part on ACOs further improving the quality of the care they provide, not merely maintaining current levels of quality. Further, we believe that the suggestions from some commenters to increase the additional quality improvement award to up to four bonus points have merit. Although we proposed the improvement measure to increase the domain score by up to 2 points, similar to other measures in the domain, we agree with commenters that increasing this to four bonus points would not appear to overweight the additional incentive since the additional bonus points can only increase a quality score by at most 25 percent overall. (That is, 4 bonus points per domain times 4 domains equals 16, which when divided by the 66 total points possible equals approximately 25 percent). Additionally, we have at least one measure (ACO #11, Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment) that is doubly weighted at 4 points in order to emphasize the importance of

adoption of EHR meaningful use. Permitting the quality improvement measure to be double weighted would similarly emphasize the importance of quality improvement, further encouraging ACOs to improve overall quality for their patient populations over time.

Final Decision: We are finalizing our proposal to provide an additional quality improvement reward for Shared Savings Program ACOs who demonstrate quality improvement on measures in a domain. We believe that this additional and explicit reward for quality improvement would complement and reinforce our current quality performance approach. Specifically, for each quality measure domain, we will award an ACO up to four additional bonus points for quality performance improvement on the quality measures within the domain. These bonus points would be added to the total points that the ACO achieves within each of the four domains. The total possible points that can be achieved in a domain, including up to 4 bonus points, could not exceed the maximum total points achievable within the domain. For example, as shown in Table 82, the total possible points for the patient/caregiver experience domain, which has eight individual measures, is 16 total possible points. Under this new policy that we are finalizing to provide for quality improvement bonus points, the maximum possible points within this domain will remain 16. If an ACO scores 12 points and is awarded four additional bonus points for quality improvement then the ACO's total points for this domain would be 16. However, if instead this same ACO had scored 13 points, then this ACO's total points after adding the bonus points would still not exceed 16. Table 82, which shows the number of points available per domain under the revised quality performance standard, reflects the current quality measure scoring methodology which will continue. Consistent with our current quality scoring methodology, the total points earned for measures in each domain, including any quality improvement bonus points up to the total possible points for the domain, would be summed and divided by the total points available for that domain to produce an overall

domain score of the percentage of points earned versus points available. The percentage score for each domain will be averaged together to generate a final overall quality performance score and sharing rate for each ACO that will be used to determine the percentage of savings it shares or, if applicable, the percentage of losses it owes, consistent with the methodology established under §425.502(e).

The calculation of the quality improvement measure for each domain would generally be based on the formula used for the MA five star rating program, as follows:

Improvement Change Score = score for a measure in performance year minus score in previous performance year.

For each qualifying measure, we will determine whether there was a significant improvement or decline between the two performance years by applying a "t-test" which is a common standard statistical test, at a 95 percent level of confidence. (See the discussion of the t-test for calculating the MA quality improvement measure in "Medicare 2014 Part C & D Star Rating Technical Notes", Attachment I, page 80, which can be downloaded from the CMS website at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html). This test assesses how unlikely it is that differences as big as those observed would be due to chance when the performance is actually the same.

The bonus points, up to a maximum of 4 points, will be awarded in direct proportion to the ACO's net improvement for the domain to the total number of individual measures in the domain. For example, there are eight individual measures for the patient/caregiver experience of care domain. If an ACO achieves a significant quality increase in all eight measures then the ACO would be awarded the maximum of four bonus points for this domain. However, if the ACO achieved a significant quality increase in only one of the eight measures in this domain and

no significant quality decline on any of the measures then the ACO would be awarded bonus points for quality improvement in the domain that is 1/8 times 4 = 0.50. The total points that the ACO could achieve in this domain could still not exceed the current maximum of 16 points shown in Table 82. We are also finalizing our proposal to add a new paragraph (4) to §425.502(e) to incorporate the new bonus points scoring methodology, but are revising the proposed language in order to reflect our decision to award up to 4 bonus points per domain.

7. Technical Corrections

Currently §425.502(d)(2)(ii) states that ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions described in §425.216(c). We note that §425.216, which addresses the actions we may take prior to termination of an ACO from the Shared Savings Program does not include a paragraph (c). To encompass all of the actions we may take prior to termination, we believe the correct reference should be to §425.216 generally, and therefore, proposed to make a technical correction to §425.502(d)(2)(ii) to eliminate the specific reference to paragraph (c) of §425.216. We also proposed to correct a typographical error in this provision by revising "actions describe" to read "actions described."

In addition, we also proposed to make a technical correction to §425.502(a)(2). This provision currently states that ACOs will be assessed on performance based on the minimum attainment level for certain measures. However, as explained above and in the November 2011 Shared Savings Program final rule (76 FR 67895 through 67896), ACO performance on a measure is assessed not only based on the minimum attainment level for the measure but also based upon the quality performance benchmark that has been established for that measure. This methodology for calculating the performance score for a measure is codified in the regulations at

§425.502(c). Accordingly, we proposed to amend §425.502(a)(2) to state that ACO performance will be assessed based on the quality performance benchmark and minimum attainment level for certain measures.

We requested comments on these proposed technical corrections.

We received no objections to correcting the typographical errors and making these other minor technical corrections and are finalizing them as proposed.

N. 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 as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM program continues CMS's initiative to increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.[13]

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 be consistent with the National and CMS Quality Strategies and other CMS quality initiatives, including the PQRS, the Shared Savings Program, and the Medicare EHR Incentive Program.

[13] Kate Goodrich, et al. "A History and a Vision for CMS Quality Measurement Programs". Joint Comm'n J. Quality & Patient Safety. 2012. 38,465, *available at* http://www.ingentaconnect.com/content/jcaho/jcjqs/2012/00000038/00000010/art00006.

- A focus on physician and eligible professional choice. Physicians and other nonphysician eligible professionals should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting eligible professionals' 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 eligible professionals. 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 eligible professionals.

4. Provisions of This Final Rule With Comment Period

As a general summary, we proposed the following VM policies in the CY 2015 PFS proposed rule:

- To apply the VM to all physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners starting in CY 2017.
- To make quality–tiering mandatory for groups and solo practitioners within Category 1 for the CY 2017 VM. Where solo practitioners and groups with two to nine eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology.
- To tailor the application of the VM to physicians and nonphysician eligible professionals participating in the Medicare Shared Savings Program (Shared Savings Program), the Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives starting in CY 2017.
- To clarify the exclusion of non-assigned claims for non-participating providers from the VM.
- To increase the amount of payment at risk under the VM from 2.0 percent in CY 2016 to 4.0 percent in CY 2017.
- To align the quality measures and quality reporting mechanisms for the VM with those available to groups and individuals under the PQRS during the CY 2015 performance period.
- To expand the current informal inquiry process to allow additional corrections for the CY 2015 payment adjustment period.

- To address the concerns raised by NQF regarding the per capita cost measures in the cost composite.

In this final rule with comment period, we discuss the proposed policies, the comments received, our responses to the comments, and a brief statement of our final policy.

Comment: We received some comments on the VM in general that were not related to any specific proposal that we made in the proposed rule. Several commenters 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. Commenters suggested that we should include the place of service where the beneficiary received care in our methodology to set cost benchmarks such that groups would be compared against other groups that treat beneficiaries who are also receiving care in that type of location.

Another commenter suggested that we add an additional adjustment for SNF CPT codes to account for higher costs of beneficiaries in this location. One commenter suggested that CMS exclude beneficiaries who receive a major organ transplant from our cost and quality measures because he believes that prospective HCC risk adjustment would not account for these added costs in the performance period. Another commenter stated that beneficiaries who receive care at home typically have high HCC scores and higher costs. This commenter suggested that CMS should consider exempting practices from the VM who treat a high number of beneficiaries with the highest HCC scores or those with more than a certain number of chronic conditions or activities of daily living dependencies, change the risk adjustment methodology to include the frailty adjuster used in the PACE program, or add "recognition of savings from expected costs."

Response: We appreciate the concerns raised by commenters and agree that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and are outside of the control of the provider. We continue to believe that our current methodology of using HCC scores that include adjustments for Medicare and Medicaid eligibility status in addition to diagnoses, and truncating costs at the 99th percentile for the highest cost beneficiaries, help address these concerns. While, the VM program does not, in the aggregate, adjust costs using an institutional risk score, the Medicare Spending per Beneficiary measure that will be used as part of the cost composite in 2014 does adjust costs based on whether a beneficiary recently required long-term institutional care as well as for whether a beneficiary is new to the Medicare program. We addressed the idea of adjusting cost measures for differences in site of service, as it pertained to hospitals, in the FY 2012 IPPS Final Rule (76 FR 51825). We continue to believe that such adjustments would undermine the ability of our measures to meaningfully capture differences in Medicare spending. 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. In 2011, an independent analysis concluded that this risk-adjustment methodology is effective at predicting actual costs, even for beneficiaries with serious or multiple chronic illnesses.[14] Moreover, the academic literature notes the multi-variant nature of care quality and the importance of defining measures across rather than simply within care settings.[15]

[14] Gregory C. Pope, et al. "Evaluation of the CMS-HCC Risk Adjustment Model: Final Report." (March 2011).
[15] Tracy E. Spinks, et al. Delivering high-quality cancer care: The critical role of quality measurement. Healthcare. 2014. 2,53-62.

We note that high costs within the post-acute and long-term care settings present a unique opportunity for these providers to improve performance on cost and quality measures. While we continue to encourage providers to report quality measures for patients in these settings and to use the information contained in their QRUR to improve and achieve high levels of performance, we will continue to monitor these groups and solo practitioners' performance under the VM and continue to explore potential risk adjustment refinements..

a. Group Size

As noted in section III.N.1, 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, we proposed to apply the VM in CY 2017 and each subsequent calendar year payment adjustment period to physicians in groups of physicians with two or more eligible professionals and to physicians who are solo practitioners (79 FR 40493-40495). For purposes of the VM, we defined a physician, a group of physicians, and an eligible professional in the CY 2013 PFS final rule with comment period (77 FR 69307-69310). We proposed to define a "solo practitioner" at §414.1205 as a single Tax Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under that TIN. We noted that this proposal to apply the VM to all solo practitioner physicians and all groups of physicians would complete our phase-in of the VM as required by the Act.

In the proposed rule, we stated our belief that we can validly and reliably apply the VM to groups with two or more eligible professionals and to solo practitioners (79 FR 40494). We noted that we conducted statistical reliability analysis on the PQRS quality measures and the VM cost measures reported in the 2010 and 2011 group and individual Quality and Resource Use Reports (QRURs) (78 FR 43500 through 43502) and found that 98 percent of the PQRS

measures included in the analysis, which were substantially similar to the PQRS measures that will be assessed during performance period CY 2015 for purposes of the VM, were highly reliable. As stated in the proposed rule, we believe that these results suggest that we can reliably apply these measures to solo practitioners and groups (79 FR 40494). In section III.N.4.h, we discuss the reliability of the all-cause readmission measure and the policy we are finalizing to address reliability concerns regarding that measure.

In Table 55 of the proposed rule, we presented the number of groups, eligible professionals, physicians, and nonphysician eligible professionals in groups of various sizes based on an analysis of CY 2012 claims with a 90-day run-out period (79 FR 40494). We estimated that our proposals to apply the VM to all groups with two or more eligible professionals and to all solo practitioners in CY 2017 would affect approximately 83,500 groups and 210,000 solo practitioners (as identified by their TINs). We further estimated that the groups consist of approximately 815,000 physicians and 315,000 nonphysician eligible professionals (79 FR 40493).

For this final rule with comment period, we have updated Table 55 from the proposed rule, using CY 2013 claims with a 90-day claim run-out period and including TINs that participated in the Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative in 2013. Table 86 shows the number of groups, eligible professionals, physicians, and nonphysician eligible professionals in groups of various sizes. We note that the number of eligible professionals includes other practitioners, such as physician assistants and nurse practitioners, in addition to physicians. We estimate that final policy to apply the VM to all physicians in groups with two or more eligible professionals and to all physicians who are solo practitioners in CY 2017 would affect approximately 900,000 physicians.

TABLE 86: Eligible Professional/Physician Group Size Distribution (2013 claims)

Group Size	Number of Groups (TINs)*	Eligible Professionals (EPs)	Number of Physicians	Number of Nonphysician EPs	Percent of Physicians	Percent of Nonphysician EPs
100+ EPs	1,345	404,738	297,175	107,563	33%	30%
50-99EPs	1,753	119,979	81,679	38,300	9%	11%
25-49 EPs	3,926	134,038	90,141	43,897	10%	12%
20-24 EPs	1,957	42,733	29,112	13,621	3%	4%
10-19 EPs	8,697	117,164	78,893	38,271	9%	11%
2-9 EPs	69,455	244,800	171,627	73,173	19%	20
1 EP	205,084	205,084	159,770	45,314	18%	13
Total	292,217	1,268,536	908,397	360,139	100%	100%

*The number of groups (TINs) include TINs that have one or more EPs participating in the Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative.

In the proposed rule (79 FR 40494), we stated that in the CY 2014 PFS final rule with comment period, we finalized the proposal that if we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the VM, and thus, are unable to calculate any of the cost measures with at least 20 cases, then the group's cost composite score would be classified as ''average'' under the quality-tiering methodology (78 FR 74780 through 74781). However, we noted this policy was codified in § 414.1270(b)(5) as a group of physicians 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 does not have at least one cost measure with at least 20 cases. We stated that we believe the regulation text at §414.1270(b)(5) better reflects the intent of this policy, and accordingly, we proposed to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780 through 74781) should be the same as the regulation text at §414.1270(b)(5). We also proposed to apply the same policy to groups and solo practitioners beginning in CY 2017. That is, a group or solo

practitioner 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 proposed to revise § 414.1270 accordingly.

We proposed to revise §414.1210 to reflect that beginning in the CY 2017 payment adjustment period, the VM would be applied to physician and nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners based on the performance period described at §414.1215 (79 FR 40495). Accordingly, we proposed to amend the regulations under subpart N to add references to solo practitioners. We solicited comments on all of these proposals.

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

Comment: We received one comment that supported our proposed definition of a “solo practitioner.”

Response: We appreciate this comment and are finalizing the definition of a “solo practitioner” to mean, “a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN.” We are codifying this definition at §414.1205.

Comment: Several commenters expressed concern that the cost measures potentially have little relevance to some provider groups and may leave some with an arbitrary label of “average” cost, if the minimum case number requirement for the cost measure is not met due to an insufficient number of beneficiaries being attributed to the group.

Response: As we stated in the CY 2014 PFS final rule with comment period (78 FR 74780), we continue to believe that groups that are attributed fewer than the minimum case size of 20 beneficiaries would not allow for the calculation of reliable cost measures. We are concerned that not classifying the group as “average” when it has fewer than 20 attributed

beneficiaries for at least one cost measure would increase the likelihood that its cost measures could fluctuate greatly from year to year. Therefore, we are finalizing our proposal that beginning in CY 2017 a group or solo practitioner 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 codifying the policy as proposed in §414.1270. We are also finalizing our proposal to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780 through 74781) for groups of physicians should be the same as the regulation text at §414.1270(b)(5).

Comment: Several commenters, citing the Secretary's statutory obligation, supported our proposal to apply the VM in the CY 2017 payment adjustment year to solo practitioner physicians and to groups of physicians with two or more eligible professionals. Other commenters opposed our proposed policy notwithstanding the statutory obligation to apply the VM to all physicians and groups of physicians beginning not later than January 1, 2017. Commenters stated that we should delay the application of the VM to all physicians, either through selective implementation or requesting that Congress amend the statute. Some commenters stated that, due to provider resource constraints, lack of access to adequate technical support, and potential lack of understanding of the information provided through the Physician Feedback Program, we should postpone the extension of the VM to smaller group practices and solo practitioners. Some commenters suggested that the VM would negatively impact physicians, especially given the proposed increase in the amount of payment at risk for CY 2017.

Response: We disagree that the VM's application to smaller groups and solo practitioners should be delayed. In addition to the statutory requirement to apply the VM to all physicians and groups of physicians beginning not later than January 1, 2017, the application of

the VM to all physician groups and solo practitioners is essential to our ongoing efforts to encourage improvement in the quality and efficiency of care provided to Medicare beneficiaries and should not be delayed. The literature highlights that the majority of patients receive care in group practices with one or two physicians[16] and that historically, smaller group practices have participated in quality improvement programs at lower rates than larger group practices.[17] Recent research also concludes that EHR-enabled small practices responded to incentives to improve quality of care on process and intermediate-outcome measures.[18] For these reasons, we believe that the application of the VM to smaller group practices and solo practitioners has the potential to incentivize increased participation in quality reporting and quality improvement activities and that smaller groups and solo practitioners have the potential to perform well under the VM.

The application of the VM to groups of two to nine eligible professionals and to solo practitioners in CY 2017 is consistent with our principle to focus on a gradual implementation of the VM. The financial impact of applying the VM to groups of two to nine eligible professionals and to solo practitioners will be eased since, we are finalizing a policy to hold them harmless from any downward payment adjustments under quality-tiering in CY 2017 (as discussed in section III.N.4.c.) and also finalizing a smaller downward payment adjustment under the VM for these groups and solo practitioners that are in Category 2 in CY 2017 (as discussed in section III.N.4.f below). Please note that in section III.N.4.b of this final rule with comment period, we are finalizing that the VM will apply to nonphysician eligible professionals in groups subject to the VM and to nonphysician eligible professionals who are solo practitioners beginning in the

[16] Sowmya R Rao, et al. Electronic health records in small physician practices: availability, use, and perceived benefits. J. Am. Med. Information Ass'n. 2011. 18, 271-275.
[17] Anne-Marie J. Audet, et al. Measure, Learn, And Improve: Physicians' Involvement in Quality Improvement. Health Affairs. 2005. 24,843-853.
[18] Naomi S. Bardach, et al., Effect of Pay-for-Performance Incentives on Quality of Care in Small Practices With Electronic Health Records. J. Amer. Med. Ass'n. 2013. 310,1051-1059.

CY 2018 payment adjustment period.

Comment: Several commenters stated that CMS should ensure that the quality and cost measures are reliable and valid for small practices and solo practitioners before expanding the VM to all physicians.

Response: Since the inception of the VM program, we have committed to establish a payment modifier that relies on a focused core set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider (77 FR 69306). Analysis of the Physician Feedback Program confirms that the measures on which the VM is based are highly reliable, especially those that are self-reported.[19] As stated in the proposed rule (79 FR 40494), we will be basing the quality of care composite on the PQRS measures selected, and reported on, by the groups (or the eligible professionals in the groups) and the solo practitioners, which enables us to recognize the diversity of reporting options for individuals and groups under the PQRS program and provide flexibility on the data they report for quality measures under the PQRS. This also allows these groups and solo practitioners the opportunity to choose measures that are relevant to their patient populations and consistent with clinical practice and high quality care. Moreover, our policy will mitigate any unintended consequences of the VM payment adjustment on smaller groups by holding harmless solo practitioner physicians and physicians in groups with two to nine eligible professionals from any downward payment adjustments under quality-tiering in CY 2017 (see section III.N.4.c of this final rule with comment period).

We conducted an additional analysis of the cost measures for the VM, using our specialty benchmarking methodology and found the per capita cost measures to be reliable for solo

[19] Mathematica Policy Research, Experience Report for the Performance Year 2012 Quality and Resource Use Reports (January 8, 2014), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2012-QRUR_Experience_Report.pdf.

practitioners and groups of two or more eligible professionals. That analysis may be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html.

Comment: Some commenters expressed concern about the VM's impact on providers who treat high-cost patients and on certain specialties, such as anesthesiology, for which few quality measures are available.

Response: The VM program continues to believe in the importance of stakeholder engagement for establishing quality metrics. To that end, we engage the National Quality Forum to pursue national endorsement of measures used in PQRS and the VM program. We are committed to using PQRS as the foundation for measurement of the performance rates for solo practitioner physicians and groups of physicians subject to the VM (77 FR 69314). Moreover, we recognized early in the VM program that the PQRS may not provide specialists and sub-specialists the flexibility to report on measures that are relevant to their unique patient panels. As discussed later, in section III.N.4.h, in previous rulemakings, we have committed to expanding the specialty measures available in the PQRS in order to more accurately measure the performance on quality of care furnished by specialists. We also reaffirm our commitment to using measures of performance across specialties that are reliable and valid for the VM program (77 FR 69315; 78 FR 74773).

Physicians have sufficient flexibility to choose the quality reporting method–PQRS GPRO web-interface, claims, registries, qualified clinical data registries, and EHR reporting mechanisms, as well as the measures on which to report information. The expansion of the GPRO to registries in 2013 and to EHRs in 2014 allowed sub-specialists to participate in PQRS as members of a group practice, such that the group could report data on measures of broad applicability (77 FR 69315). The claims-based outcome measures used in the VM afford groups

and solo practitioners an additional opportunity to earn a quality composite score that is above average. Where a group or solo practitioner falls in Category 1 under the VM (that is, meets the criteria to avoid the CY 2017 PQRS payment adjustment), but the group or solo practitioner does not have at least 20 cases for each PQRS measure on which it reports as required for inclusion in the quality composite of the VM, the group or solo practitioner's quality composite score would be based on the three claims-based outcome measures described at §414.1230, provided that the group or solo practitioner has at least 20 cases for at least one of the claims-based outcome measures.

In addition, as discussed in section III.N.4.h of this final rule with comment period, eligible professionals and groups should note that PQRS has a Measure Applicability Validation (MAV) process. MAV determines PQRS incentive eligibility or potential applicability of the payment adjustment for eligible professionals and groups reporting less than nine measures across three domains or nine or more across less than three domains. We recommend that commenters refer to the Measure Application Validation (MAV) Process to alleviate concerns that lack of applicable measures would result in an automatic downward adjustment under the VM . http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. Also, please refer to section III.K.2 of this final rule with comment period for the final 2017 policies for MAV and the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

Comment: Commenters cited that solo practitioners and groups with 2 to 24 eligible professionals, who received a QRUR in fall 2014, will have a short period of time to analyze their performance data and to prepare for the CY 2015 performance period.

Response: On September 30, 2014, we made Quality and Resource Use Reports

(QRURs) available to all group of physicians and physicians who are solo practitioners based on their performance in CY 2013. As we stated in the CY 2015 proposed rule (79 FR 40494-95), we believe that we have provided small groups and solo practitioners sufficient time to understand how the VM works and how to participate in the PQRS. We are sensitive to groups and solo practitioners who may need adequate lead time to understand the impact of the beneficiary attribution method used for the VM. At the time that we made our proposal to apply the VM to solo practitioners and groups of 2 to 25 EPs, available research suggested that the information provided in the QRURs is relevant to solo practitioners and groups for future quality improvement efforts. Published literature suggests that, of the beneficiaries assigned in one year to a group practice under the Shared Savings Program attribution rule, which is substantially similar to the one used in the VM program – 80 percent were assigned to that same group practice the following year.[20] In response to commenters' concerns, we also conducted an additional analysis using the VM attribution methodology and determined that, of the beneficiaries assigned to a given TIN for the five cost and 3 outcome measures included in the VM for 2017, approximately 76% were assigned to the same TIN for these measures, in both 2012 and 2013.

More importantly, we believe our final policy to hold harmless groups with two to nine eligible professionals and solo practitioners from any downward payment adjustments under quality-tiering in CY 2017 would likely mitigate unintended consequences that could occur (see section III.N.4.c of this final rule). We note that in the 2013 QRUR Experience Report, which will be released in the next few months, we will provide a detailed analysis of the impact of the 2015 VM policies on groups of 100 or more eligible professionals subject to the VM in CY

[20] J. Michael McWilliams, et al. Outpatient Care Patterns and Organizational Accountability in Medicare. 2014. 174,938-945.

2015, including findings based on the data contained in the 2013 QRURs for all groups of physicians and solo practitioners.

Comment: Several commenters believed that physicians had have little experience with the PQRS program and physicians generally do not understand the methodology used to calculate the VM and therefore urged CMS to increase its outreach and education efforts. One commenter urged CMS to publicly share the VM methodology, as well as the results of the reliability and validity testing of the measures used in the calculation of the VM.

Response: In response to the comments about physicians not being familiar with the PQRS program or not understanding the methodology used to calculate the VM, we strongly encourage physicians to proactively educate themselves about the PQRS and VM programs by visiting the PQRS website http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html and VM/QRUR website http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html. The PQRS website contains detailed information about how groups and individual eligible professionals can participate in the PQRS program, including information on how to avoid the PQRS payment adjustment. The VM/QRUR website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html) contains information on the VM policies for each applicable payment adjustment year, including detailed information on the methodology used to calculate the CY 2015 VM shown in the CY 2013 QRURs and how to use the information contained in the QRURs. We note that we work with medical and specialty associations throughout the year to educate them about the PQRS and VM programs and the QRURs. Further outreach will be also be undertaken by our Quality Improvement Organizations (QIOs), who 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.

As we expand the application of the VM to all physicians, we will continue to monitor the VM program and continue to examine the characteristic of those groups of physicians and solo practitioners that could 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.

After considering the public comments, we are finalizing the proposal and regulation text at §414.1210(a)(3) that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more eligible professionals and to physicians who are solo practitioners based on the performance period described at §414.1215. We are finalizing the definition of a "solo practitioner" at §414.1205 and amending the regulations under subpart N to add references to solo practitioners. We are also finalizing our proposal and the regulation text at § 414.1270(c)(5) that beginning in CY 2017 a group or solo practitioner 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. We are also finalizing our proposal to clarify that the description of this policy in the preamble of the CY 2014 PFS final rule with comment period (78 FR 74780 through 74781) for groups of physicians should be the same as the regulation text at §414.1270(b)(5).

b. Application of the VM to Nonphysician EPs

As noted above, section 1848(p) of the Act requires that we establish the VM and apply it to items and services furnished under the PFS beginning on January 1, 2015, for specific physicians and groups of physicians the Secretary determines appropriate, and beginning not later than January 1, 2017, for all physicians and groups of physicians. Section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to eligible

professionals as defined in section 1848(k)(3)(B) of the Act. As previously finalized in the CY 2013 PFS final rule with comment period, in payment adjustment years CY 2015 and CY 2016, we will apply the VM to Medicare payments for items and services billed under the PFS by physicians in groups (as identified by their Medicare-enrolled TIN) subject to the VM, but not to the other eligible professionals that also may bill under the TIN (77 FR 69312). We finalized in the CY 2013 PFS final rule with comment period (77 FR 69307 through 69310) that physicians, as defined in section 1861(r) of the Act, include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors.

In section III.N.4.a of this final rule with comment period, we finalized our proposal to apply the VM in the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period to physicians in groups of physicians with two or more eligible professionals and to physicians who are solo practitioners as required by section 1848(p)(4)(B)(iii)(II) of the Act.

In the CY 2015 PFS proposed rule, based on the Secretary's discretion under section 1848(p)(7) of the Act, we proposed to apply the VM beginning in the CY 2017 payment adjustment period to all of the eligible professionals in groups with two or more eligible professionals and to eligible professionals who are solo practitioners (79 FR 40495-40496). That is, we proposed to apply the VM beginning in CY 2017 to the items and services billed under the PFS by all of the physicians and nonphysician eligible professionals who bill under a group's TIN. We proposed to apply the VM beginning in CY 2017 to groups that consist only of nonphysician eligible professionals (for example, groups with only nurse practitioners or physician assistants). We also proposed to modify the definition of "group of physicians" under §414.1205 to also include the term "group" to reflect these proposals. We also proposed to apply

the VM beginning in CY 2017 to nonphysician eligible professionals who are solo practitioners. Additionally, we proposed that physicians and nonphysician eligible professionals would be subject to the same VM policies established in earlier rulemakings and under 42 CFR part 414, subpart N. For example, nonphysician eligible professionals would be subject to the same amount of payment at risk and quality-tiering policies as physicians. We proposed to modify the regulations under 42 CFR part 414, subpart N, accordingly.

We finalized in the CY 2013 PFS final rule with comment period (77 FR 69307 through 69310) that, for purposes of establishing group size, we will use the definition of an eligible professional as specified in section 1848(k)(3)(B) of the Act. This section defines an eligible professional as any of the following: (1) a physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act: physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietician, or nutrition professional; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist.

Beginning CY 2017, under our proposal, the VM would apply to all of the eligible professionals, as specified in section 1848(k)(3)(B) of the Act, that bill under a group's TIN based on the TIN's performance during the applicable performance period. During the payment adjustment period, all of the nonphysician eligible professionals who bill under a group's TIN would be subject to the same VM that would apply to the physicians who bill under that TIN.

This proposal was consistent with our stated principle that the VM should focus on shared accountability (77 FR 69307). We continue to believe that the VM can facilitate shared accountability by assessing performance at the group practice level and by focusing on the total costs of care, not just the costs of care furnished by an individual physician.

Moreover, section 1848(p)(5) of the Act requires us to, as appropriate, apply the VM "in a manner that promotes systems-based care." We stated in the CY 2013 PFS proposed rule that, in this context, systems-based care is the processes and workflows that (1) make effective use of information technologies, (2) develop effective teams, (3) coordinate care across patient conditions, services, and settings over time, and (4) incorporate performance and outcome measurements for improvement and accountability.[21] (77 FR 44996) We stated in the CY 2015 PFS proposed rule, we believe that applying the VM to all of the eligible professionals in a group, rather than only the physicians in the group, would enhance the group's ability and resources to redesign processes and workflows to achieve these objectives and furnish high-quality and cost-effective clinical care with greater care coordination (79 FR 40496).

As mentioned above, we also proposed to apply the VM to groups that consist only of nonphysician eligible professionals, as well as solo practitioners who are nonphysician eligible professionals beginning in CY 2017 (79 FR 40496). Consistent with the application of the VM to groups of physicians and groups that contain both physicians and nonphysician EPs, the quality of care composite for groups that consist only of nonphysician EPs and solo practitioner nonphysician EPs would be based on the quality data submitted under the PQRS at the group or individual level in accordance with our existing policy. To the extent we are able to attribute beneficiaries to these groups and solo practitioners under the attribution methodology proposed in section III.N.4.j of the proposed rule to calculate cost measures, we proposed to calculate the cost composite using those cost measures. If a cost composite could not be calculated for a group or solo practitioner, then we proposed to classify the group or solo practitioner's cost

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21 Johnson JK, Miller SH, Horowitz SD. Systems-based practice: Improving the safety and quality of patient care by recognizing and improving the systems in which we work. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches, Vol 2: Culture and Redesign. AHRQ Publication No. 08-0034-2. Rockville, MD: Agency for Healthcare Research and Quality; August 2008. p. 321-330.

composite as "average" as specified in §414.1270. We solicited comments on all of our proposed policies for applying the VM to nonphysician eligible professionals beginning in CY 2017.

The following is summary of the comments we received on all of our proposed policies for applying the VM to nonphysician eligible professionals beginning in CY 2017.

Comment: Several commenters supported our proposal to apply the VM to nonphysician eligible professionals beginning in CY 2017. These commenters stated that the proposal would support the goal of shared accountability and urged CMS to include their cost and quality data in the QRURs. Some of the commenters wanted nonphysician eligible professionals to be held harmless from any downward payment adjustments under the VM.

Most of the commenters urged CMS to delay implementation of the VM for nonphysician eligible professionals and suggested that CMS adopt a phased approach that gives nonphysician eligible professionals more time to understand and prepare for the implementation of the VM. One commenter was specifically concerned about nonphysician eligible professionals who are solo practitioners or in groups with two to nine eligible professionals not having time to prepare for the implementation of the VM. Commenters expressed concern that nonphysician eligible professionals have not been sufficiently prepared for the VM because: prior PFS rules did not indicate that nonphysician eligible professionals may be included in the VM in the future; nonphysician eligible professional groups have not yet received a QRUR; nonphysician eligible professionals have not received targeted education regarding application of the VM to them; and the proposal does not allow nonphysician eligible professionals the same phased-in approach to the VM that CMS provided to physician groups. One commenter recommended that CMS not apply the VM to nonphysician eligible professionals until CMS adopts meaningful specialty designations. Other commenters indicated that some nonphysician

eligible professionals groups will not be attributed cost measures since they do not bill evaluation and management codes. A few commenters were concerned about the low participation rates of nonphysician eligible professionals in the PQRS program. A few commenters proposed a phased-in approach for implementation of the VM for nonphysician eligible professionals, which they stated would be consistent with the implementation of the VM for physician groups.

Response: We agree with the commenters that nonphysician eligible professionals would benefit from additional time to become familiar with participation in the PQRS program and the VM methodology. Therefore, we are not finalizing our proposal to apply the VM beginning in the CY 2017 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and to nonphysician eligible professionals who are solo practitioners. Instead, we are finalizing that we will apply the VM beginning in the CY 2018 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and to nonphysician eligible professionals who are solo practitioners. We added paragraph (a)(4) to §414.1210 to reflect this policy. We note that in the CY 2015 PFS proposed rule, we did not propose a performance period for the CY 2018 payment adjustment period for the VM. The performance periods we have established in prior rulemaking for the VM have been two calendar years prior to the beginning of the payment adjustment year (for example, CY 2013 was the performance period for the VM applied in CY 2015). We expect to propose the performance period for the CY 2018 payment adjustment period for the VM in the CY 2016 PFS proposed rule.

We believe that delaying the implementation of the VM to nonphysician eligible professionals until CY 2018 is consistent with our stated objective to focus on gradual implementation of the VM. The delay would also provide additional time for nonphysician eligible professionals to learn about how to participate in the PQRS program and to become

knowledgeable about the policies for calculating the VM. Information about the VM is available on the VM/QRUR website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html.

Under our final policy, we will apply the VM beginning in CY 2018 to the items and services billed under the PFS by all of the physicians and nonphysician eligible professionals who bill under a group's TIN. We are finalizing that we will apply the VM beginning in CY 2018 to groups that consist only of nonphysician eligible professionals (for example, groups with only nurse practitioners or physician assistants). Beginning in CY 2018, the VM will apply to all of the eligible professionals, as specified in section 1848(k)(3)(B) of the Act, that bill under a group's TIN based on the TIN's performance during the applicable performance period. During the payment adjustment period, all of the nonphysician eligible professionals 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 are finalizing the proposed modification to the definition of "group of physicians" under §414.1205 to also include the term "group" to reflect these final policies. We are also finalizing the policy to apply the VM beginning in CY 2018 to nonphysician eligible professionals who are solo practitioners.

Additionally, we are finalizing that beginning in CY 2018, physicians and nonphysician eligible professionals will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician eligible professionals will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We are finalizing the proposed modifications to the regulations under subpart N accordingly.

However, since CY 2018 will be the first year that groups that consist only of nonphysician eligible professionals and solo practitioners who are nonphysician eligible professionals will be subject to the VM, we are finalizing a policy to hold these groups and solo

practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. We will add regulation text under §414.1270 to reflect this policy when we establish the policies for the VM for the CY 2018 payment adjustment period in future rulemaking.

c. Approach to Setting the VM Adjustment Based on PQRS Participation

In the CY 2014 PFS final rule with comment period (78 FR 74767-74768), we adopted a policy to categorize groups of physicians subject to the VM in CY 2016 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2016 VM into two categories. Category 1 includes groups of physicians that (a) meet the criteria for satisfactory reporting of data on PQRS quality measures through the GPRO for the CY 2016 PQRS payment adjustment or (b) do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, if the PQRS-qualified clinical data registry reporting mechanism is selected) must be met during the CY 2014 reporting period for the PQRS CY 2016 payment adjustment. For the CY 2016 VM, Category 2 includes those groups of physicians that are subject to the CY 2016 VM and do not fall within Category 1. For those groups of physicians in Category 2, the VM for CY 2016 is -2.0 percent.

We proposed to use a similar two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners (79 FR 40496). To continue to align the VM with the PQRS and accommodate the various ways in which EPs can participate in the PQRS, for purposes of the CY 2017 VM, we proposed that Category 1 would include 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 mechanisms, as proposed in section III.K of the proposed rule) for the CY 2017 PQRS payment adjustment. Our proposed criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2017 are described in section III.K of the proposed rule. We also proposed to include in Category 1 groups that do not register to participate in the PQRS as a group practice participating in the PQRS group practice reporting option (GPRO) in CY 2015 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (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 for the CY 2017 PQRS payment adjustment, all as proposed in section III.K of the proposed rule. We noted that these proposals are consistent with the policies for inclusion in Category 1 as established for the CY 2016 VM (78 FR 74767 through 74768). We would maintain the 50 percent threshold for the CY 2017 VM as we expand the application of the VM to all groups and solo practitioners in CY 2017. Our proposed criteria for satisfactory reporting by individual eligible professionals for the claims, EHR, and registry reporting mechanisms and for satisfactory participation in a qualified clinical data registry for the CY 2017 PQRS payment adjustment are described in section III.K of the proposed rule. Lastly, we proposed to include in Category 1 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-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as proposed in section III.K of the proposed rule. Category 2 would

include those groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. As discussed in the proposed rule (79 FR 40505), for CY 2017, we proposed to apply a -4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. We solicited comment on these proposals.

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

Comment: A number of commenters supported our proposal to continue to account for eligible professionals that participate in the PQRS as individuals in the determination of groups and solo practitioners that would be in Category 1. One commenter indicated that our proposals allow groups to have the flexibility to choose a PQRS reporting mechanism that best fits the practice. One commenter did not support the use of both group and individual reporting mechanisms to determine whether a group falls in Category 1, indicating that it makes comparisons among groups that choose to report as a group compared to a group whose eligible professionals report as individuals inequitable.

Response: We appreciate commenters' support for our proposal to provide a way to combine individually reported PQRS measures into a group score for purposes of the CY 2017 VM. In response to the commenter's concern about the use of the individual reporting mechanisms in the VM, we believe that the use of both the individually reported PQRS measures and the PQRS GPRO measures to calculate the quality composite of the VM recognizes recognize the diversity of physician practices and the various measures used to assess quality of care furnished by these practices. 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, we expect to continue to align the VM with the PQRS program requirements and reporting mechanisms to ensure physicians and groups of physicians report data on quality measures that reflect their practice.

Furthermore, we do not believe that comparing quality composite scores based on PQRS GPRO measures or individually reported PQRS measures would create inequities because a group's performance reflects the underlying eligible professionals on whose behalf the group reports and the quality measure benchmarks are inclusive of data gathered through both PQRS GPRO and individually-reported PQRS measures. Lastly, we note that the inclusion of individual PQRS measure in the VM provides an additional mechanism and reduces additional reporting burden for groups that are subject to the VM and do not report under the PQRS as a group to avoid an automatic VM downward payment adjustment.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners as proposed. For purposes of the CY 2017 VM, Category 1 will include 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, as finalized in section III.K of this final rule with comment period) for the CY 2017 PQRS payment adjustment. Our final criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PQRS payment adjustment for CY 2017 are described in Table 51 in section III.K of this final rule with comment period. We also are finalizing to include in Category 1 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 eligible professionals 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 for the CY 2017 PQRS payment adjustment, all as finalized in Table 50 in section III.K of this final rule with comment

period. Our final criteria for satisfactory reporting by individual eligible professionals for the claims, EHR, and registry reporting mechanisms and for satisfactory participation in a qualified clinical data registry for the CY 2017 PQRS payment adjustment are described in section III.K of this final rule with comment period. Lastly, we are finalizing to include in Category 1 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-qualified clinical data registry for the CY 2017 PQRS payment adjustment, all as finalized in Table 50 in section III.K of this final rule with comment period. Category 2 will include those groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. We will continue to explore how to include additional data for specialists, including potentially incorporating Hospital VBP Program performance into the VM, as discussed in section III.N.4.k of this final rule with comment period. We would adopt any such changes through future notice and comment rulemaking. As discussed in section III.N.4.f of this final rule with comment period, for CY 2017, we are finalizing policies to (1) apply a -4.0 percent VM to groups with 10 or more eligible professionals that fall in Category 2, and (2) apply a -2.0 percent VM to groups with two to nine eligible professionals and solo practitioners that fall in Category 2.

For a group and a solo practitioner subject to the CY 2017 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 2015 for the CY 2017 PQRS payment adjustment. As noted in section III.5.g of this final rule with comment period earlier, CY 2015 is the performance period for the CY 2017 payment adjustment period for the VM.

In the CY 2014 PFS final rule with comment period (78 FR 74768-74770), we finalized that the quality-tiering methodology will apply to all groups in Category 1 for the VM for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we finalized that groups of physicians in Category 1 with between 10 and 99 eligible professionals would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 VM.

For the CY 2017 VM, we proposed to continue a similar phase-in of the quality-tiering based on the number of eligible professionals in the group (79 FR 40497). We proposed to apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with two to nine eligible professionals and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. That is, we proposed that solo practitioners and groups with two to nine eligible professionals in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM. Accordingly, we proposed to revise §414.1270 to reflect these proposals. We believe this approach would reward groups and solo practitioners that provide high-quality/low-cost care, reduce program complexity, and would also fully engage groups and solo practitioners into the VM as we complete the phase-in of the VM in CY 2017. We solicited comments on these proposals.

We stated in the CY 2015 PFS proposed rule (79 FR 40497) that we believe it is appropriate to hold groups with two to nine eligible professionals and solo practitioners in Category 1 harmless from any downward adjustments under the quality-tiering methodology, which is similar to the policy we apply to groups with between 10 and 99 eligible professionals during the first year the VM applies to them (CY 2016). We noted that we anticipate applying the CY 2018 VM with both upward and downward adjustments based on a performance period of CY 2016 to all groups and solo practitioners, and therefore, we would make proposals in future rulemaking accordingly.

We stated that, for groups with between 10 and 99 eligible professionals, we believe it is appropriate to begin both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.4.a. of this final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how all TINs fare under the policies established for the VM for the CY 2015 payment adjustment period. As noted above, we are considering providing semi-annual QRURs with updated cost and resource use information to groups and solo practitioners. Then, during the summer of 2015, we intend to disseminate QRURs based on CY 2014 data to all groups and solo practitioners, and the reports would show how all TINs would fare under the policies established for the VM for the CY 2016 payment adjustment period. The QRURs will also

include additional information about the TINs' performance on the MSPB measure, individually-reported PQRS measures, and the specialty-adjusted cost measures.

Thus, we stated that we believe groups with between 10 and 99 eligible professionals will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with 10 or more eligible professionals in 2017.

Based on an analysis of CY 2012 claims, we estimate that approximately 6 percent of all eligible professionals are in a Category 1 TIN that would be classified in tiers that would earn an upward adjustment by having a composite score that is at least 1 standard deviation away from the mean composite and it is statistically significant, approximately 11 percent of all eligible professionals are in a Category 1 TIN that would be classified in tiers that would receive a downward adjustment by having a composite score that is at least 1 standard deviation away from the mean composite and it is statistically significant, and approximately 83 percent of all eligible professionals are in a Category 1 TIN that would receive no payment adjustment in CY 2017. These results suggest that our quality-tiering methodology identifies a small number of groups and solo practitioners that are outliers – both high and low performers – in terms of whose payments would be affected by the VM, thus limiting any widespread unintended consequences.

We stated in the CY 2015 PFS proposed rule that we will continue to monitor the VM program and continue to examine the characteristics of those groups that could 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: Several commenters supported applying quality-tiering to all groups and solo practitioners. One commenter did not support the concept of quality-tiering and indicated that it should be voluntary for all practices. Most commenters strongly supported our proposal to hold harmless groups with two to nine eligible professionals and solo practitioners from downward payment adjustments in CY 2017, although one commenter suggested that CMS should apply downward adjustments to them. Some commenters supported our proposal to apply upward, neutral, or downward payment adjustment to physician groups with 10 or more eligible professionals. However, many commenters had concerns about applying the downward adjustment to groups with 10 or more eligible professionals, since we proposed a maximum downward adjustment of -4.0 percent. A commenter indicated that there is a substantial operational difference between large practices and small practices since larger practices have more resources and revenue and are better suited to absorb downward payment adjustments under the VM. Some commenters were concerned that implementation of the downward adjustment to smaller physician practices, particularly given that the downward adjustment is slated to be -4.0 percent in 2017, may negatively impact beneficiary access to care. Other comments stated that solo practitioners and groups with two to twenty-four eligible professionals would not have a QRUR until the fall 2014 and will have little time to analyze their performance data. A number of commenters recommended more intermediate, phased-in approach to the downward adjustment such as holding harmless groups with less than 25 eligible professionals, 50 eligible professionals, or all groups regardless of size. Commenters suggested that we give only upward or neutral payment adjustments to all groups and solo practitioners or keep the CY 2016 policies in place for the CY 2017 VM. One commenter suggested that physician groups be able to file for a hardship exception with CMS in the event they face a downward adjustment

under the VM. One commenter suggested that the payment adjustments under quality-tiering apply to all groups regardless of size so that primary care physicians who practice in larger groups are not disadvantaged, while another suggested that CMS should not change the program in 2017. Some commenters requested demographic information about the outliers that would receive upward or downward adjustments based on quality-tiering.

Response: We appreciate the commenters' support of our proposal to apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017 and to hold solo practitioners and groups with two to nine eligible professionals in Category 1 harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM. We disagree with commenters who suggested that we should not apply upward, neutral, or downward payment adjustments derived under the quality-tiering methodology to physician groups with 10 or more eligible professionals in CY 2017. For groups with 10 or more eligible professionals, we believe it is appropriate to apply both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.a. of this final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. We believe that groups of 10 or more eligible professionals will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with 10 or more eligible professionals in 2017.

With regard to the commenters' concerns over the impact of the proposed maximum -4.0 percent downward adjustments on small practices, as discussed in section III.N.4.f of this final rule with comment period, we are finalizing a policy to apply a -2.0 percent VM to groups with two to nine eligible professionals and solo practitioners that fall in Category 2. We believe the revised policy will alleviate some of the commenters' concerns about the financial impact of applying quality-tiering to small groups and solo practitioners in CY 2017.

With regard to the suggestion that physicians in groups of 10 to 24 eligible professionals have not had sufficient experience with the quality measures used in the VM, we note that on September 30, 2014, we made QRURs available to all group of physicians and physicians who are solo practitioners based on their performance in CY 2013. Each QRUR contains the group or solo practitioner's performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how the TIN would fare under the policies established for the VM for the CY 2015 payment adjustment period. As we stated in the CY 2015 PFS proposed rule, we believe it is appropriate to hold groups with two to nine eligible professionals and solo practitioners in Category 1 harmless from any downward adjustments under the quality-tiering methodology, which is similar to the policy we apply to groups with between 10 and 99 eligible professionals during the first year the VM applies to them (CY 2016). For groups with between 10 and 99 eligible professionals, we believe it is appropriate to begin both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2017 VM. We believe that these groups have had sufficient time to understand how the VM works and how to participate in the PQRS. We note that the 2013 QRUR Experience Report, as described in section III.N.4.a of this final rule, will also contain additional information about the groups that were determined to have cost and/or quality performance that was significantly different than average, as determined under the policies established for the VM for

the CY 2015 payment adjustment period. We reiterate our belief that the final policies will reward groups and solo practitioners that provide high-quality/low-cost care, reduce program complexity, and will also fully engage groups and solo practitioners into the VM as we complete the phase-in of the VM in CY 2017.

After considering the public comments received, we are finalizing the application of the quality-tiering methodology to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with two to nine eligible professionals and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, solo practitioners and groups with two to nine eligible professionals in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM.

d. Application of the VM to Physicians and Nonphysician Eligible Professionals that Participate in the Shared Savings Program, 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 CY 2015 and CY 2016 to groups of physicians that participate in the Shared Savings Program Accountable Care Organizations (ACOs), the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or other similar Innovation Center 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 VM, and CY 2014 for the CY 2016 VM).

Although section 1848(p)(4)(B)(iii)(I) of the Act gives the Secretary discretion to apply the VM beginning on January 1, 2015 to specific physicians and groups of physicians the Secretary determines appropriate, section 1848(p)(4)(B)(iii)(II) of the Act requires application of the VM beginning not later than January 1, 2017 to all physicians and groups of physicians. Therefore, as discussed in section III.N.4.a. of this final rule with comment period, we proposed to apply the VM to all physicians in groups with two or more eligible professionals and to solo practitioners who are physicians starting in CY 2017. In section III.N.4.b of this final rule with comment period, we discussed our proposal to also apply the VM starting in CY 2017 to all nonphysician eligible professionals in groups with two or more eligible professionals and to solo practitioners who are nonphysician eligible professionals. We describe in this section how we proposed to apply the VM beginning in the CY 2017 payment adjustment period to the physicians and nonphysician eligible professionals in groups, as well as those who are solo practitioners, participating in the Shared Savings Program, Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives.

(1) Physicians and Nonphysician Eligible Professionals that Participate in ACOs under the Shared Savings Program

(a) Application of the VM to participants in the Shared Savings Program. Beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners participating in the Shared Savings Program (79 FR 40497). Groups and solo practitioners participate in the Shared Savings Program as part of an ACO as provided in section 1899 of the Act. Under the Shared

Savings Program, an ACO may consist of multiple participating groups and solo practitioners (as identified by the ACO participants' TINs). As of April 1, 2014, there are 338 ACOs participating in the Shared Savings Program. This number includes 31 ACOs that consist of only one ACO participant TIN. The ACO submits quality data on behalf of all the ACO participant TINs in that ACO under the Shared Savings Program.

Comment: Many commenters suggested that we should continue to exempt Shared Savings Program participants from the VM. These commenters stated that because participants in the Shared Savings Program have already taken on accountability for quality improvement and cost reduction, it is unnecessary and confusing to apply the VM to these providers. Several commenters suggested that this option is available under the existing language of the statute or that, if CMS believes it does not have this authority, we should seek it from Congress. Commenters also expressed concern that applying the VM to participants in the Shared Savings Program would cause inappropriate comparisons of performance and create confusion by sending mixed signals about cost and quality benchmarks. Several of these commenters stated that organizations participating in Shared Savings Program and Pioneer ACOs are making significant investments and that they believe this further underscores the importance of allowing these groups to focus on one set of pay for performance metrics to avoid creating additional investment costs. A few commenters supported the application of the VM to Shared Savings Program participants because they believe that applying the VM broadly will encourage value-based change.

Response: We disagree with commenters who believe we should continue to exempt groups and solo practitioners who participate in the Shared Savings Program from the VM. We are required under section 1848(p)(4)(B)(iii)(II) of the Act to apply the VM to all physicians and groups of physicians no later than January 1, 2017, and we believe that alignment of these

programs emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. We understand the concerns presented by the commenters regarding calculation of the cost and quality composites under the VM, and we address them below, in sections III.N.4.d.1(b) and (c) of this final rule with comment period.

After considering the public comments on this proposal, we are finalizing our policy to apply the VM, beginning with the CY 2017 payment adjustment period, to physicians in groups with two or more eligible professionals and physicians who are solo practitioners that participate in an ACO under the Shared Savings Program.

We note that, in response to commenters' concerns, we are not finalizing the proposal to apply the VM to nonphysician eligible professionals in the CY 2017 payment adjustment period that participate in an ACO under the Shared Savings Program, consistent with the final policy for groups and solo practitioners that do not participate in the Shared Savings Program as discussed in section III.N.4.b of this final rule with comment period. Also, consistent with our policy discussed in section III.N.4.b to apply the VM beginning with the CY 2018 payment adjustment period to nonphysician eligible professionals who are not in an ACO under the Shared Savings Program, we will apply the VM beginning with the CY 2018 payment adjustment period to nonphysician eligible professionals in groups with two or more eligible professionals and nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program. We further note that, based in part on concerns identified by commenters, we are finalizing policies in sections III.N.4.d.1 (b) and (c) of this final rule with comment period that take into consideration a group or solo practitioner's participation in an ACO under the Shared Savings Program during the performance period for the VM, rather than participation during the payment adjustment period for the VM as proposed.

(b) Calculation of the cost composite of the VM for Shared Savings Program participants. Beginning with the CY 2017 payment adjustment period, we proposed to classify the cost composite for the VM as "average cost" for groups and solo practitioners (as identified by the ACO's participant TINs) that participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017) (79 FR 40498). We proposed to apply "average cost" to these groups and solo practitioners regardless of whether they participated in the Shared Savings Program during the performance period (for example, in CY 2015 for the CY 2017 VM). We believe that it would not be appropriate to apply the quality-tiering methodology to calculate the cost composite for these groups and solo practitioners because of the differences in the methodology used to calculate the cost benchmarks under the Shared Savings Program and the VM. Under the Shared Savings Program, cost benchmarks are based on the actual historical Medicare fee-for-service expenditures for beneficiaries that would have been assigned to the ACO during the historical benchmark period, and are updated to reflect changes in national FFS spending; however, the cost benchmarks under the VM are based on national averages. We believe that these are significant differences in the methodology for calculating the cost benchmarks under the two programs. Consequently, we believe that any attempt to calculate the VM cost composite for groups and solo practitioners participating in the Shared Savings Program using the VM quality-tiering methodology would create two sets of standards for ACOs for their cost performance. We believe that having two sets of standards for participants in ACOs for cost performance would be inappropriate and confusing and could send conflicting messages and create conflicting incentives. We solicited comments on our proposals to classify the cost composite as "average cost" for groups and solo practitioners who participate in the Shared Savings Program during the payment adjustment period.

For groups and solo practitioners who participate in the Shared Savings Program during the performance period (for example, CY 2015), but no longer participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017), we proposed to apply the quality-tiering methodology to calculate the cost composite for the VM for the payment adjustment period based on the groups' and solo practitioners' performance on the cost measures, as identified under §414.1235, during the performance period (79 FR 40499). We stated that it would be appropriate to calculate their cost composite under the quality-tiering methodology because these groups and solo practitioners are no longer part of the Shared Savings Program during the payment adjustment period.

Comment: As noted above, many commenters expressed concern that applying the VM to ACO participants in the Shared Savings Program would cause inappropriate comparisons of performance and create confusion by sending mixed signals about cost benchmarks. Several of these commenters who were opposed to the application of the VM to Shared Savings Program ACO participants suggested that we should continue to exempt Shared Savings Program participants from the VM, but stated that if we were to apply the VM to Shared Savings Program ACO participants, we should classify the cost composite as "average cost" because of the differing methodologies for assessing cost performance for the VM and the Shared Savings Programs. A few commenters stated that groups or solo practitioners participating in the Shared Savings Program should have their cost composite calculated without regard to participation in the Shared Savings Program and disagreed with our proposed policy because it limits the potential upward adjustment under the VM available to groups and solo practitioners participating in the Shared Savings Program.

Response: We understand the concerns presented by these commenters that calculating a cost composite for these groups and solo practitioners could cause confusion and send mixed

signals. The VM and Shared Savings Programs are sufficiently different such that it would be counterproductive at this point in the programs' development to measure groups and solo practitioners using different cost measures under each program. To allow Shared Savings Program participants to focus their energy and resources on the Shared Savings Program targets for slowing expenditure growth, a different approach under the VM program for groups and physicians participating in the Shared Savings Program is appropriate. We will finalize our proposal to classify the cost composite for groups and solo practitioners participating in an ACO under the Shared Savings Program as "average cost" to avoid confusion and prevent conflicting incentives for these providers who have already committed to reducing cost growth through their participation in the Shared Savings Program. We plan to investigate the possibility of calculating a VM cost composite at the ACO level in the future, so that groups and solo practitioners in ACOs would have the opportunity to earn the full upward adjustment in the future, and we would address this issue in future rulemaking.

Comment: We received several comments objecting to our proposal to take into account a group or solo practitioner's participation in a Shared Savings Program ACO during the payment adjustment period for the VM. A few commenters did not support our proposal to apply "average cost" to groups and solo practitioners that join a Shared Savings Program ACO in the payment adjustment period, but were not in a Shared Savings Program ACO in the performance period. These commenters pointed out that this policy could discourage groups and solo practitioners from joining an ACO if it would mean they would not receive an earned upward adjustment in the payment adjustment period. One of these commenters suggested that groups or solo practitioners should be given the option to have their cost composite calculated under the quality-tiering methodology if they were not in an ACO in the performance period. Several commenters suggested that all groups and solo practitioners should be given the

opportunity to "opt in" to having their cost composite calculated regardless of whether they were in an ACO in the performance period. Another commenter objected to our proposal to apply the quality-tiering methodology to calculate the cost composite for groups and solo practitioners that participate in the Shared Savings Program in the performance period but do not participate in the Shared Savings Program during the payment adjustment period. The commenter suggested that these groups should be classified as "average cost" because they would have been working toward ACO cost benchmarks during the performance year.

Response: We are convinced by commenters who raised concerns with our proposal to consider a group or solo practitioner's participation in a Shared Savings Program ACO during the payment adjustment period for the purpose of determining the applicability of the VM to the group or solo practitioner. We believe that commenters have accurately pointed out that Shared Savings Program ACO participants would be working toward a specified set of quality and cost metrics during the performance period, and that the performance period would therefore, best define their status as a Shared Savings Program participant for the purpose of determining the applicability of the VM during the associated payment adjustment period. We agree with the points raised in the comments about assessing a group or solo practitioner under the VM cost measures and benchmarks in the payment adjustment period if that group or solo practitioner was participating in an ACO under the Shared Savings Program in the performance period. A group or solo practitioner is unlikely to know two years in advance that it plans to leave an ACO, and we do not believe it would appropriate to assess the group or solo practitioner under a different set of cost measures than those that the group or solo practitioner had been working toward in the performance period as part of an ACO. As stated in our proposed rule (79 FR 40498), we believe that having two sets of standards for ACOs for cost performance would be inappropriate and confusing. We believe that the Shared Savings Program has the potential to reduce expenditure

growth and improve quality and we do not want to discourage groups or solo practitioners from participating in that program (79 FR 40498). Consistent with that stated intent, and in light of the comments we received pointing out the potential conflict if we were to calculate a cost composite for groups and solo practitioners that participated in an ACO under the Shared Savings Program but did not participate in the payment adjustment period, we believe it is appropriate to apply "average cost" to all groups and solo practitioners that participate in an ACO under the Shared Savings Program in the performance period regardless of whether the group or solo practitioner remains in the ACO in the payment adjustment period. We do not, however, believe that it would be appropriate to use an "opt in" policy for groups or solo practitioners participating in Shared Savings Program ACOs. We believe that allowing groups and solo practitioners who participate in the Shared Savings Program in the performance period to "opt in" to having their cost composite calculated would conflict with our intent to avoid setting multiple financial benchmarks for these groups and solo practitioners.

After considering the public comments received, we are finalizing our policy to classify the cost composite as "average cost" for groups and solo practitioners that participate in an ACO under the Shared Savings Program. Unlike our proposed policy, which considered participation in a Shared Savings Program ACO during the payment adjustment period for the VM (for example, CY 2017), we are finalizing a policy that, if a group or solo practitioner participates in a Shared Savings Program ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then that group or solo practitioner's cost composite will be classified as "average cost," regardless of whether the group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period. In addition to addressing some of the concerns raised by commenters, we believe this final policy is consistent with our existing policy for CYs 2015 and 2016, under

which a group's participation in the Shared Savings Program during the performance period (CYs 2013 and 2014, respectively) is relevant for purposes of determining whether to exempt the group from application of the VM during the relevant payment adjustment period. Further, utilizing the performance period for the purpose of determining whether the group or solo practitioner is a Shared Savings Program ACO participant eliminates the need for us to calculate preliminary payment adjustment factors prior to the beginning of the payment adjustment period, and then recalculate the payment adjustment factors after the final ACO participation list is completed, as we had proposed to do (79 FR 40506).

As requested by commenters, this final policy is also simpler than our proposal, because it does not take into account a group's status during the payment adjustment period.

(c) Calculation of the quality composite under the VM for Shared Savings Program participants. Beginning with the CY 2017 payment adjustment period, we proposed to calculate the quality of care composite score for the VM for groups and solo practitioners who participate in an ACO under the Shared Savings Program in accordance with the following policies (79 FR 40498-40499):

- We proposed to calculate the quality of care composite score based on the quality-tiering methodology using quality data submitted by the ACO, as discussed in section III.N.4.h of this final rule with comment period, from the performance period and apply the same score to all of the groups and solo practitioners under the ACO during the payment adjustment period. In other words, using CY 2017 as an example, we proposed to calculate the quality of care composite score for the CY 2017 VM for all of the groups and solo practitioners participating in the ACO in CY 2017 based on the ACO's CY 2015 quality data. We note that in section III.N.4.h of this final rule with comment period, we are finalizing our proposal to exclude the claims-based outcome measures identified under §414.1230 from the calculation of the quality of

care composite score for groups and solo practitioners who participate in the Shared Savings Program as described in section III.N.4.d.1 of this final rule with comment period.

- For groups and solo practitioners who participate in the ACO during the payment adjustment period (for example, CY 2017) and either did not participate in the Shared Savings Program or were part of a different ACO during the performance period (for example, CY 2015), we proposed to calculate the quality of care composite score based on the quality-tiering methodology using the quality data submitted by the ACO from the performance period. For example, if a group or solo practitioner is in ACO 1 during CY 2017, and either was not in the Shared Savings Program or was part of ACO 2 during CY 2015, we would use ACO 1's quality data from CY 2015 to calculate the quality of care composite. This approach is consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). In other words, if a professional changes groups from TIN A in the performance period to TIN B in the payment adjustment period, we would apply TIN B's VM to the professional's payments for items and services billed under TIN B during the payment adjustment period.

- If the ACO did not exist during the performance period (for example, CY 2015), then we would not have the ACO's quality data to use in the calculation of the quality of care composite score for the payment adjustment period (for example, CY 2017). Therefore, if the ACO exists during the payment adjustment period but did not exist during the performance period, we proposed to classify the quality of care composite for all groups and solo practitioners who participate in the ACO during the payment adjustment period as "average quality" for the payment adjustment period. We proposed to apply this policy to groups and solo practitioners regardless of their status during the performance period – in other words, regardless of whether they participated in the Shared Savings Program as part of a different ACO, or did not exist

during the performance period (for example, a TIN forms or newly enrolls in Medicare after the end of the performance period). We believed this proposal was appropriate since we would not have the ACO's quality data from the performance period to calculate a quality of care composite for all of the groups and solo practitioners participating in the ACO during the payment adjustment period. We noted that some of these groups and solo practitioners may have participated in the PQRS during the performance period; therefore, we would have quality data for those groups and solo practitioners. If they were part of a different ACO during the performance period, then we would also have that ACO's quality data. We stated that we did not, however, believe that it would be appropriate to use the groups' and solo practitioners' PQRS or other ACO quality data from the performance period to calculate a quality of care composite because the groups and solo practitioners are part of a new ACO during the payment adjustment period. We stated our belief that this approach would be consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). In this case, if a TIN's status changes from the performance period to the payment adjustment period (that is, participating in ACO 2 or not participating in the Shared Savings Program in the performance period, to participating in ACO 1 in the payment adjustment period), then we proposed that we would not "track" or "carry" ACO 2's quality data or the TIN's PQRS quality data to determine the quality of care composite for groups and solo practitioners who participate in ACO 1.

- For groups and solo practitioners who participate in the Shared Savings Program during the performance period (for example, CY 2015) but no longer participate in the Shared Savings Program during the payment adjustment period (for example, CY 2017), we proposed to classify the quality of care composite as "average quality" for the VM for the payment adjustment period. Since these groups and solo practitioners were part of an ACO during the

performance period, we would have the ACO's quality data from that period. We stated that we did not believe it would be appropriate to use the ACO's quality data from the performance period to calculate a quality of care composite because the groups and solo practitioners are no longer part of the ACO during the payment adjustment period. We stated this approach is also consistent with our policy not to "track" or "carry" an individual professional's performance from one TIN to another TIN (see 77 FR 69308 through 69310). Even though we proposed to classify the quality of care composite for these groups and solo practitioners as "average quality," we solicited comments on whether we should use the ACO's quality data from the performance period to calculate the quality composite for these groups and solo practitioners for the payment adjustment period.

We solicited comments on all of our proposals to calculate the quality composite for groups and solo practitioners participating in the Shared Savings Program. We provided a summary of the proposals in the proposed rule in Table 56 using TIN A and ACO 1 and ACO 2 as examples (79 FR 40499).

Comment: As noted above, in the discussion of the cost composite, we received many comments stating that we should exempt groups and solo practitioners from the 2017 VM. Many commenters also suggested an "Innovation Pathway" approach for participants in the Shared Savings Program and Innovation Center initiatives. Under this suggested approach, groups and solo practitioners participating in the Shared Savings Program or other Innovation Center initiatives would receive "average cost" and "average quality" unless they opted to have their VM calculated. The reasoning behind this approach, provided by commenters, is to allow ACOs and the participating groups and solo practitioners to focus on one set of cost and quality benchmarks and avoid confusion predicted by some commenters. Many commenters also believe that applying the VM to these groups and solo practitioners could lead to "double

counting" positive or negative performance. A few commenters stated that if we are to apply the VM to groups and solo practitioners in the Shared Savings Program, they should only be subject to a neutral or an upward adjustment. Some commenters supported our proposed policies related to cost and quality composites, and one commenter stated that if the VM is applied to these groups, they believed that only a quality composite should be calculated because they believe that ACOs are already rewarded for reducing costs. We also received comments on the specific quality measures and benchmarks that we proposed to use for the VM for groups and solo practitioners participating in the Shared Savings Program, which we address in section III.N.4.h of this final rule with comment period.

Response: We appreciate commenters' concern about the potential for conflicting incentives on cost and quality performance when applying the VM to Shared Savings Program participants given that these participants are already working toward a set of cost efficiency and quality improvement goals through the Shared Savings Program. We continue to believe, however, that it is appropriate to calculate a quality composite for groups and solo practitioners participating in the Shared Savings Program based on the ACO's quality data. We appreciate the support of commenters who agreed that it is appropriate to calculate a quality composite for these groups and solo practitioners based on the ACO's quality data. We disagree with commenters who believe it would be inappropriate to calculate a VM for groups and solo practitioners that participate in the Shared Savings Program because this could be seen as "double counting" performance. We believe that application of the VM to providers who participate in the Shared Savings Program reinforces the importance of quality improvement and quality reporting by offering participants in the Shared Savings Program an opportunity to earn an upward adjustment for improved performance. We agree with the commenter who stated if calculating a VM for Shared Savings Program participants, we should only calculate the quality

composite. However, we would like to point out that the Shared Savings Program does also reward high quality care in addition to rewarding reductions in cost growth. Unlike the differences between the methodologies for evaluating costs under the Shared Savings Program and the VM, we do not believe that the differences between the quality methodologies for these two programs will create significant confusion or conflicting incentives. Because the GPRO web interface measures are consistent across the VM and Shared Savings Program, we believe that it will not create undue burden on ACO participants or cause significant confusion to calculate a quality composite for these groups and solo practitioners. More specifically, the cost measures and cost benchmarks used to determine the cost composite under the VM are different than the methodology used to calculate financial performance under the Shared Savings Program. In contrast, the GPRO web interface quality measures used in the Shared Savings Program are the same as those used to calculate the quality composite of the VM for groups that are not in Shared Savings Program ACOs that report through GPRO. Furthermore, ACOs in the Shared Savings Program report on quality measures on behalf of all the groups and solo practitioners that participate in the ACO, which allows us to calculate a single quality composite that can be applied to all participants. We do not have this same capability for the cost composite, which would need to be calculated separately for each group or solo practitioner and thus could create conflicting incentives and add more confusion. By calculating a quality composite for groups and solo practitioners that participate in ACOs under the Shared Savings Program we are providing an additional incentive to improve the quality of care for their beneficiaries. As stated in section III.N.4.d.1.b., where we discuss the calculation of the cost composite for Shared Savings Program ACO participants, we do not believe it would be appropriate to allow groups or solo practitioners to “opt in” to having their VM calculated based on the TIN’s, rather than the whole ACO’s, performance. Allowing groups or solo practitioners to “opt in” to having their own VM

calculated could create conflicting incentives and competing priorities between the ACO's goals and the specific group's or solo practitioner's goals. An "opt in" policy would result in Shared Savings Program ACO participants reporting quality data outside of the ACO, which is not consistent with the policies of the Shared Savings Program.

Comment: As noted in the section III.N.4.d.1.b., we received a few comments related to scenarios in which a group or solo practitioner enters or leaves the Shared Savings Program. Commenters pointed out that applying an ACO's quality performance to groups or solo practitioners that were not in the ACO in the performance period could discourage groups and solo practitioners from joining an ACO in the payment adjustment period if it would mean they would not receive an earned upward adjustment. One commenter indicated that it would not be fair to assess a group or solo practitioner that was in the Shared Savings Program in the performance period, but is not in the payment adjustment period, without consideration of the incentives in place in the performance period. This commenter, however, did not object to the application of "average quality" to groups and solo practitioners in this situation. We also received some general comments that the many different scenarios proposed were confusing and added additional complexity to the VM program.

Response: We appreciate the comments that pointed out the potential problems with using participation during the payment adjustment period to determine the quality performance of groups and solo practitioners. As stated in the comments and responses in section III.N.4.d.1.b., we agree that using a group or solo practitioner's status in the payment adjustment period could discourage future participation in the Shared Savings Program. Consistent with our response to the cost composite comments, we believe that it would be inappropriate to ignore the quality performance of a group or solo practitioner in the performance period because they choose to join an ACO in the payment adjustment period, as well as in the opposite scenario (if a

group or solo practitioner participated in an ACO in the performance period and then left the ACO in the payment adjustment period). As discussed in our earlier response, we believe it would be appropriate to use the ACO's quality performance because the group or solo practitioner was part of the ACO during the performance period and should be assessed based on the incentives that existed during the performance period. Our proposal to consider a group or solo practitioner's participation in a Shared Savings Program ACO during the payment adjustment period was intended to be consistent with our existing policy to not "track" or "carry" an individual's performance from one TIN to another from performance period to payment adjustment period. Given the comments we received on our proposals concerning the cost and quality composites for groups and solo practitioners that participate in an ACO under the Shared Savings Program, we agree that it is preferable to consider a group or solo practitioner's participation in an ACO during the performance period to determine how the VM should be applied. Given that we would have ACO-level quality data available for group and solo practitioners that were in an ACO in the performance period, we believe this data should be used to calculate a quality composite for those groups and solo practitioners. This is consistent with the policy regarding the cost composite that we are finalizing in section III.N.4.d.1.b of this final rule with comment period, which focuses on the cost and quality performance incentives that existed for the group or solo practitioner in the performance period, not the payment adjustment period when applying the VM to groups and solo practitioners that are in the Shared Savings Program. As noted above, it is also consistent with the way in which we have determined participation in the Shared Savings Program for the 2015 and 2016 VM, based on whether the group or solo practitioner participated in the Shared Savings Program during the performance period. Further, as noted in the cost composite section III.N.4.d.1.b, utilizing the performance period for the purpose of determining whether the group or solo practitioner is a Shared Savings

Program ACO participant eliminates the need for us to calculate preliminary payment adjustment factors prior to the beginning of the payment adjustment period, and then recalculate the payment adjustment factors after the final ACO participation list is completed, as we had proposed to do (79 FR 40506). We are also convinced by commenters who stated that our proposed policies were too complex. We believe that using a TIN's participation in an ACO in the performance period to determine the cost composite, while considering the TIN's status in the payment adjustment period to determine the quality composite, would add unnecessary complexity and inconsistency, especially as new ACOs continue to be established and existing ACOs expand.

In the proposed rule (79 FR 40498), we stated that if a group or solo practitioner was in ACO 2 in the performance period and then joined ACO 1 in the payment adjustment period, we would use ACO 1's quality performance to calculate the quality composite for that group or solo practitioner. Although we did not receive specific comments on this policy, we believe that based on the other comments received and the policy we are finalizing it would no longer be appropriate to use ACO 1's quality data to calculate a quality composite for these groups and solo practitioners. Given that in all other scenarios, we are finalizing policies that we will consider the group or solo practitioner's (as identified by taxpayer identification number (TIN)) status during the performance period, rather than the payment adjustment period to determine how the group's or solo practitioner's quality and cost composite should be calculated, we also believe this is the appropriate approach for groups and solo practitioners that move between ACOs. We have previously stated our rationale for using the performance period to determine a TIN's association with an ACO and we believe that reasoning applies to this scenario as well. Furthermore, it would be unnecessarily complex to apply a different policy for groups and solo practitioners in this scenario (where the TIN is part of one ACO during the performance period

and a different ACO during the payment adjustment period) than in the other scenarios previously discussed.

After considering the public comments received, we are finalizing a policy to calculate a quality of care composite score based on the quality-tiering methodology using quality data submitted by a Shared Savings Program ACO during the performance period and apply the same quality composite to all of the groups and solo practitioners, as identified by TIN, under that ACO. Unlike our proposed policy, which considered whether a group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period for the VM (for example, CY 2017), our final policy is if a group or solo practitioner participates in a Shared Savings Program ACO during the applicable performance period (for example, the CY 2015 performance period for the CY 2017 payment adjustment period), then that group or solo practitioner's quality composite is calculated using the ACO-level quality data from the performance period, regardless of whether the group or solo practitioner participates in a Shared Savings Program ACO during the payment adjustment period. The VM calculated under this policy will apply to all physicians billing under the group's TIN in the CY 2017 payment adjustment period, and beginning in the CY 2018 payment adjustment period, to all physician and nonphysician eligible professionals billing under the group's TIN, regardless of whether the professional was part of the group in the performance period. This is consistent with our policy for other groups subject to the VM, in that we will not "track" or "carry" an individual professional's performance from one TIN to another TIN.

Comment: Several commenters requested that we provide further guidance on how groups that leave the Shared Savings Program will be treated under the VM. Specifically one commenter suggested that we consider how we would apply the VM in situations in which an ACO dissolves mid-year and does not report quality data. The commenter stated that we should

ensure that those groups and solo practitioners participating in the ACO are not subject to the automatic downward adjustment.

Response: We appreciate commenters raising these questions and concerns. We did not specifically address in the proposed rule 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 clarify 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 40496 – 40497). We are finalizing this policy for groups and solo practitioners that participate in a Shared Savings Program ACO under §414.1210(b)(2). Consistent with the application of the VM to other groups and solo practitioners that report under PQRS as described in section III.N.4.c, 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 as described in section III.N.4.f. We also plan to issue program-specific guidance to provide participants with more information about how these various situations may be addressed. Our final policy focusing on the group or solo practitioner's status in the performance period will simplify the operational issues related to determining the answers to these questions.

(d) Treatment of groups with two to nine eligible professionals and solo practitioners in the Shared Savings Program. In section III.N.4.c of this final rule with comment period, we discussed our proposal to hold groups with two to nine eligible professionals and solo

practitioners who are in Category 1 harmless from any downward adjustments under the quality-tiering methodology for the CY 2017 payment adjustment period. We proposed to also hold harmless from any downward adjustments groups with two to nine eligible professionals and solo practitioners who participate in ACOs under the Shared Savings Program during the CY 2017 payment adjustment period based on their size during the performance period. We would follow our established process for determining group size, which is described at §414.1210(c). Therefore, to the extent that a quality of care composite can be calculated for an ACO, and the cost composite would be classified as "average cost," groups with 10 or more eligible professionals participating in the Shared Savings Program would be subject to an upward, neutral, or downward payment adjustment in CY 2017, and groups with two to nine eligible professionals and solo practitioners would be subject to an upward or neutral payment adjustment in CY 2017. We also proposed that groups and solo practitioners participating in ACOs under the Shared Savings Program would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries, as proposed in section III.N.4.f. We proposed to modify §414.1210 to reflect these proposals.

Comment: We did not receive any comments on these proposals specific to the Shared Savings Program. General comments on these proposals are addressed in section III.N.4.c of this final rule with comment period.

Consistent with final policies in this final rule with comment period to use a group or solo practitioner's status in the performance period to determine participation in the Shared Savings Program, we are finalizing a policy to hold harmless from any downward adjustments groups with two to nine eligible professionals and solo practitioners who participate in ACOs under the Shared Savings Program during the performance period (for example, the CY 2015 performance

period for the CY 2017 payment adjustment period) based on their size during the performance period.

We have modified §414.1210 to reflect these final policies for application of the VM beginning with the CY 2017 payment adjustment period to groups and solo practitioners that participate in an ACO under the Shared Savings Program ACO.

(2) Physicians and Nonphysician Eligible Professionals that Participate in the Pioneer ACO Model, the Comprehensive Primary Care (CPC) Initiative, or Other Similar Innovation Center Models or CMS Initiatives

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce Medicare, Medicaid, or Children's Health Insurance Program (CHIP) expenditures, while preserving or enhancing the quality of care furnished to beneficiaries under those programs. Therefore, all models tested by the Innovation Center would be expected to assess participating entities (for example, providers, ACOs, states) based on quality and cost performance. As noted above, we established a policy in the CY 2013 PFS final rule with comment period (77 FR 69313) to not apply the VM in CY 2015 and CY 2016 to groups of physicians that are participating in the Pioneer ACO Model, the CPC Initiative, or in other Innovation Center initiatives or other CMS programs which also involve shared savings and where participants make substantial investments to report quality measures and to furnish higher quality, more efficient and effective healthcare.

The Pioneer ACO Model and the CPC Initiative are scheduled to end on December 31, 2016. Therefore, the relevant performance periods for consideration for participants in these initiatives are CY 2015 for the CY 2017 VM payment adjustment period and potentially CY 2016 for the CY 2018 VM payment adjustment period. Under the Pioneer ACO Model, an ACO

may consist of practitioners from multiple participating groups and solo practitioners (as identified by their individual TIN/NPI combination). Thus, a group practice may consist of one or more eligible professionals who participate in the Pioneer ACO Model and other eligible professionals who do not participate in the Pioneer ACO Model. In the case of the CPC Initiative, a practice site may participate in the model even if one or more other practice sites that use the same TIN does not participate.

(a) Application of the VM to participants in the Pioneer ACO Model and CPC Initiative. Beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative during the relevant performance period in accordance with the policies described below (79 FR 40500).

Comment: The majority of comments we received stated that CMS should not apply the VM to group practices and solo practitioners participating in the Pioneer ACO Model or CPC Initiative. These comments largely mirrored the comments summarized in section III.N.4.d.1.a of this final rule with comment period regarding the application of the VM to Shared Savings Program participants. A few commenters also suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. Additionally, one organization expressed concern that the number of varying approaches to calculating the VM in our proposed rule would be too complex to implement and may not create equitable comparisons among Pioneer, CPC, other Innovation Center model participants, and other individuals and groups under the VM program. This commenter suggested that we exempt group practices and solo practitioners who participate in the Pioneer ACO Model until that

model ends. As noted in section III.N.4.d.1.a, a few commenters supported the application of the VM to as many groups and solo practitioners as possible to encourage value-based change.

Response: We are required to apply the VM to all physicians and groups of physicians beginning no later than January 1, 2017, and we believe that alignment of the VM program and the Pioneer ACO Model, CPC Initiative, and other similar models emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. We understand the concerns presented by these commenters and summarized in section III.N.4.d.1 regarding calculation of the cost and quality composites under the VM, and we address them below, in section III.N.4.d.2.b of this final rule with comment period.

After considering the public comments on this proposal, we are finalizing a policy to apply the VM in the CY 2017 payment adjustment period, to physicians in groups with two or more eligible professionals in which at least one eligible professional participates in the Pioneer ACO Model or the CPC Initiative during the performance period, and to physicians who are solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period.

We note that, in response to commenters' concerns, we are not finalizing the proposal to apply the VM to nonphysician eligible professionals in the CY 2017 payment adjustment period that participate in the Pioneer ACO Model or CPC Initiative. This policy is consistent with the policy for the Shared Savings Program in the CY 2017 payment adjustment period described in section III.M.4.d.1 and for groups and solo practitioners that do not participate in these models or in the Shared Savings Program, as discussed in section III.N.4.b of this final rule with comment period.

(b) Calculation of the cost and quality composite of the VM for Pioneer ACO and CPC Initiative participants.

● For groups and solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative during the performance period for the VM, we proposed policies for how we would calculate the cost and quality composites in a number of scenarios depending on whether or not all eligible professionals in the group participate in the model, whether or not the group or solo practitioner report through PQRS outside of the model, and if so, through which reporting mechanism, and whether or not the group or solo practitioner participate in the Shared Savings Program in the payment adjustment period. Additionally, we described several alternatives that we considered to the proposed policies. Specifically, we described two alternatives to Scenario 2 described in the proposed rule (79 FR 40501). Under one alternative, for groups that have some eligible professionals participating in the model and some eligible professionals that are not participating in the model, we considered applying "average quality" without regard to any PQRS data reported outside of the model. Another alternative we considered was to apply ''average quality'' to groups where less than 50 percent of all eligible professionals in the group meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals or satisfactorily participate in a PQRS-qualified clinical data registry, because we would not have quality data for more than half of the group that we could use to calculate a quality composite. For a detailed description of these scenarios and proposed policies, as well as the alternatives considered, we refer readers to the proposed rule at 79 FR 40500-40504. We also provided a summary of these proposals, as Table 57 in the proposed rule (79 FR 40504).

We solicited comments on these proposals and the alternatives considered.

Comment: We received comments on our proposals for calculating the quality and cost composites for Pioneer ACO Model and CPC Initiative participants. As noted in section

III.N.4.d.2.a of this final rule with comment period, most commenters did not support our proposal to apply the VM to Pioneer ACO and CPC participants in general. However, many of these commenters stated that if the VM were to be applied to these providers, then CMS should classify the cost and quality composites as average to avoid sending what they see as conflicting messages about cost and quality benchmarks. These commenters did not make any distinction between the reporting mechanism used when quality data is reported to PQRS outside of the model (for example, GPRO vs. individual reporting). Instead, they argued that we should apply average cost and average quality for all groups and solo practitioners participating in these models because they have already taken on accountability for cost and quality measures, and it would be confusing and unnecessary to hold them to a different set of measures or benchmarks. The "Innovation Pathway" suggestion referenced in the summary of comments on section III.N.4.d.1 was also recommended for groups and solo practitioners participating in the Pioneer Model and CPC Initiative. A few commenters suggested that providers participating in Pioneer or CPC should only be eligible for upward VM adjustments. Some commenters suggested that groups and solo practitioners should be able to opt-in to having their cost and quality composites calculated as described in the proposed rule. We also received a comment indicating that providers in the Pioneer and CPC models should have their VM calculated the same as any other TIN subject to the VM.

Response: We are convinced by commenters who suggested that groups and solo practitioners in these models should be classified as "average cost" and "average quality." In section III.N.4.d.1, we described our rationale for classifying the cost composite as "average" for groups and solo practitioners that participate in an ACO under the Shared Savings Program. Similar to the Shared Savings Program, the Pioneer ACO Model and CPC Initiative use a shared savings methodology that is significantly different than the cost measures and benchmarks used

to calculate the cost composite under the VM program. Because of these significant differences, we are persuaded by commenters who stated that the calculating a cost composite for groups and solo practitioners in these models could create conflicting incentives. Moreover, it is challenging to meaningfully assess the quality performance of groups that participate in these models for purposes of calculating a quality composite for the VM given that for many of these groups, some eligible professionals in the group participate in these models while other eligible professionals within the same group do not participate (79 FR 40502). Although the Pioneer ACO Model uses the same set of quality measures as the Shared Savings Program, this quality data does not necessarily represent all eligible professionals in the group because some do not participate in the model. The CPC Initiative presents similar challenges because of groups in which only a subset of eligible professionals may be participating in the model. Because some of the groups with eligible professionals participating in these models could choose to report outside of the model through a PQRS reporting mechanism, we may have quality data for a subset of groups or for a subset of individuals within a group, depending on the reporting mechanism. The policies in our proposed rule indicated that we would make use of this quality data when available, however, as noted above, we also considered other options including applying "average quality" to certain groups. We agree that it is important for these participants to focus on the cost and quality measures within their respective models and are persuaded by the vast majority of commenters who indicated that these policies could create conflicting incentives for model participants and several commenters who stated that they were unnecessarily complex and likely to cause confusion. We do not agree with commenters who suggested giving groups and solo practitioners an opportunity to "opt-in" for the reasons stated in response to comments on section III.N.4.d.1. We appreciate the support of commenters who agreed that applying the VM to groups and solo practitioners in these initiatives would support the VM

program goals of improving quality and cost efficiency. To the extent possible, we intend to provide QRURs showing cost and, where available, quality performance on VM measures, to these groups and solo practitioners to further support the goals of the VM program.

Comment: We also received comments on our proposal to calculate the cost composite for groups and solo practitioners who are not in the Shared Savings Program or similar CMS initiative in the payment adjustment year. These commenters stated that groups and solo practitioners should be assessed based on the cost and quality incentives that were in place in the performance period, not the payment adjustment period. Under our proposed policies, we would calculate a cost composite for groups that participated in Pioneer or CPC in the performance period but did not participate in another similar initiative or the Shared Savings Program in the payment adjustment period. One commenter stated these groups and solo practitioners should be classified as average cost because at least a portion of their eligible professionals were operating under a different set of cost measures during the performance period.

Response: As noted in section III.N.4.d.1, we are persuaded by commenters who suggested that taking into account the status of the group or solo practitioner in the payment adjustment period does not fully acknowledge the incentives that existed for the group or solo practitioner in the performance period and, consistent with the approach taken for Shared Savings Program participants, we are finalizing a policy that takes into account whether a group or solo practitioner participates in the Pioneer ACO Model or CPC Initiative during the performance period for the VM. As discussed above, we believe the differences in methodology between the VM cost measures and the methodologies used to determine shared savings under the Pioneer ACO Model and the CPC Initiative are significant and that it would be inappropriate to calculate a cost composite for these groups and solo practitioners. In the proposed rule (79 FR 40502), we stated that for groups and solo practitioners that participate in the Pioneer ACO

Model or CPC Initiative in the performance period and then participate in an ACO under the Shared Savings Program in the payment adjustment period, we would use the Shared Savings Program ACO's quality data to calculate the quality composite, or classify the quality composite as average if the ACO did not exist in the performance period. We are modifying this policy such that groups or solo practitioners who participate in the Pioneer ACO Model or CPC Initiative in the performance period and then participate in an ACO under the Shared Savings Program in the payment adjustment period will also receive "average cost" and "average quality". This is consistent with the policies we are finalizing for the groups and solo practitioners that participate in an ACO under the Shared Savings Program to consider the group or solo practitioner's status during the performance period, in order to determine how the VM will be applied.

After considering the public comments, we are finalizing a policy that for solo practitioners and groups with at least one eligible professional 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. This policy is similar to the alternative to scenario 2 we considered in the proposed rule (79 FR 40501), though with a broader application to address commenters' concerns about the level of complexity in the proposals. We are not finalizing our proposals regarding the requirements for groups and solo practitioners in the Pioneer ACO Model and CPC Initiative to avoid Category 2 and the downward payment adjustment. Instead, for the CY 2017 payment adjustment period, the policy to classify the cost composite as "average cost" and the quality composite as "average quality" will apply to all solo practitioners who participate in the Pioneer ACO Model or the CPC Initiative in the performance period and all groups with at least one eligible professional who participates in the Pioneer ACO Model or the CPC Initiative in the performance period. Given the concerns about distracting from the goals of the models in which

these groups and solo practitioners participate, the complexity of determining whether groups that have some eligible professionals in the model and some who are not in the model successfully reported quality performance data, and the commenters' requests for a simpler policy, we believe this is an appropriate policy.

The VM calculated under this policy will apply to all physicians billing under the group's TIN in the CY 2017 payment adjustment period regardless of whether the physician was part of the group in the performance period. This is consistent with our policy for other groups subject to the VM, in that we will not "track" or "carry" an individual professional's performance from one TIN to another TIN.

(c) Treatment of groups of two to nine eligible professionals and solo practitioners that participate in the Pioneer ACO Model or CPC Initiative.

In section III.N.4.c of this final rule with comment period, we discussed our proposal to hold groups with two to nine eligible professionals and solo practitioners who are in Category 1 harmless from any downward adjustments under the quality-tiering methodology for the CY 2017 payment adjustment period. We proposed to also hold harmless from any downward adjustments for CY 2017 groups with two to nine eligible professionals, where one or more eligible professionals participate in the Pioneer ACO Model or the CPC, and solo practitioners who participate in the Pioneer ACO Model or the CPC during the CY 2015 performance period based on their size during the performance period. We would follow our established process for determining group size, which is described at §414.1210(c). We also proposed that groups where one or more eligible professionals participate in the Pioneer ACO Model or the CPC during the performance period, and solo practitioners participating in the Pioneer ACO Model or the CPC during the performance period would be eligible for the additional upward payment adjustment of +1.0x for caring for high-risk beneficiaries, as proposed in section III.N.4.f below.

Comment: We did not receive comments specific to this proposal. The comments we received on our general policy to hold harmless groups of two to nine eligible professionals and solo practitioners are discussed in III.N.4.a of this final rule with comment period.

Given the modified policy we are finalizing for group practices and solo practitioners participating in the Pioneer ACO Model and CPC Initiative to classify the cost composite as "average cost" and the quality composite as "average quality," these proposals are no longer relevant and will not be finalized.

(d) In addition, beginning with the CY 2017 payment adjustment period, we proposed to apply the VM to physicians and nonphysician eligible professionals in groups with two or more eligible professionals and to physicians and nonphysician eligible professionals who are solo practitioners who participate in other similar Innovation Center models or CMS initiatives during the relevant performance period for the VM in accordance with the proposed policies described above for the Pioneer ACO Model and the CPC Initiative. We are unable to propose an exhaustive list of the models and initiatives that would fall under this category because many of them have not yet been developed. In addition, it is possible that the timeline for implementing some of these new models and initiatives may not coincide with the timeline for rulemaking for the VM. To address these issues, we proposed to rely on the following general criteria to determine whether a model or initiative would fall in this "other similar" category and thus would be subject to the policies described above for the Pioneer ACO Model and the CPC Initiative: (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 included in this "other similar" category. Rather, the criteria are intended to serve as a general framework for evaluating models and initiatives with regard to the application of the VM to groups and solo practitioners who participate (79 FR 40502). We solicited public comment on these or other appropriate criteria for determining which models or initiatives we should classify as "other similar" models, for the purposes of applying the policies for the Pioneer ACO Model and the CPC Initiative described above.

Comment: We did not receive any comments on the criteria proposed to determine "other similar" models, though many of the comments received on our proposals related to the application of the VM to groups and solo practitioners participating in the Shared Savings Program, Pioneer ACO Model, or CPC Initiative.

Response: As stated in our response to comments on the application of the VM to Pioneer ACO and CPC Initiative participants, we are convinced by commenters who suggested that we apply "average cost" and "average quality" to these groups and solo practitioners. We believe many of these "other similar" models would be testing new quality measures, reporting methods, or both, and we want to encourage innovation, including standing up new infrastructure to capture performance on quality measures that could be used in the VM program in the future.

After consideration of the comments, we are finalizing our general criteria as proposed for determining if a model or initiative should be classified as an "other similar" model or initiative. We will apply the final policies adopted for applying the VM to groups and solo practitioners that participate in the Pioneer Model or the CPC Initiative to Innovation Center models and CMS initiatives that we determine are "similar" based on these criteria.

We recognize that the policies we finalize for the Pioneer ACO Model and the CPC Initiative might not be applicable to all of the various models and initiatives that could be developed in future years. If we believe a different approach to applying the VM would be appropriate for a model or initiative, we intend to address it in future rulemaking. In addition, if we were to determine that a model or initiative falls under this "other similar" category based on the general criteria, we will provide notice to participants in the model or initiative through the methods of communication that are typically used for the model or initiative.

Additionally, consistent with our final policies for the Pioneer ACO Model and CPC Initiative, Shared Savings Program, and groups and solo practitioners that do not participate in these programs or models, we will not apply the VM to nonphysician eligible professionals in similar Innovation Center models or CMS initiatives in the CY 2017 payment adjustment period.

We modified §414.1210 to reflect all of these policies.

In addition to the comments described above, we received a few comments that were outside the scope of what was proposed in this rule:

Comment: One commenter stated that ACOs should have an opportunity to receive confidential reports on their performance on all Medicare FFS beneficiaries – not just MSSP-attributed beneficiaries – through the Physician Feedback Program prior to application of the VM program. This commenter also stated that CMS should reduce the administrative burden associated with the "opt out" process for data sharing for Shared Savings Program ACOs. Other commenters stated that CMS should adjust the financial benchmarks for ACOs based on VM adjustments.

Response: We appreciate the input from these commenters but believe these suggestions are outside the scope of this rule. Data sharing policies and financial benchmarking methodologies for the Medicare Shared Savings Program are described in the Final Rule for that

program released in November 2011. The rule can be accessed http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf. Information on the Pioneer ACO Model, can be found here: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/.

e. Clarification Regarding Treatment of Non-assigned Claims for Non-Participating Physicians

In the CY 2013 PFS final rule with comment period in which we established a number of key policies for the VM, we stated that we had received few comments on our proposal to apply the VM to the Medicare paid amounts for the items and services billed under the PFS so that beneficiary cost-sharing or coinsurance would not be affected (77 FR 69309). These commenters generally agreed with the proposal to apply the VM to the Medicare paid amounts for the items and services billed under the PFS at the TIN level so that beneficiary cost-sharing would not be affected. Therefore, we finalized this policy and accordingly established a definition of the VM at §414.1205 that was consistent with the proposal and the statutory requirement to provide for differential payment to a physician or a group of physicians under the fee schedule based upon the quality of care furnished compared to cost during a performance period.

We continue to believe that it is important that beneficiary cost-sharing not be affected by the VM and that the VM should be applied to the amount that Medicare pays to physicians. However, in previous rulemaking, we did not directly address whether the VM would be applied to both assigned services for which Medicare makes payment to the physician, and to non-assigned services for which Medicare makes payment to the beneficiary. Participating physicians are those who have signed an agreement in accordance with section 1842(h)(1) of the Act to accept payment on an assignment-related basis for all items and services furnished to Medicare beneficiaries. In other words, participating physicians agree to accept the Medicare approved amount as payment in full and to charge the beneficiary only the Medicare deductible

and coinsurance amount. In contrast, non-participating physicians have not signed an agreement to accept assignment for all services furnished to beneficiaries, but they can still choose to accept assignment for individual services. If they choose not to accept assignment for particular services, non-participating physicians can charge the beneficiary more than the Medicare-approved amount, up to a limit called the "limiting charge." The limiting charge is defined at section 1848(g)(2)(C) of the Act as 115 percent of the recognized payment amount for nonparticipating physicians. In contrast, if a non-participating physician chooses to accept assignment for a service, they receive payment from Medicare at the approved amount for non-participating physicians, which is 95 percent of the fee schedule amount. 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.

For assigned claims, Medicare makes payment directly to the physician. In accordance with section 1848(p)(1) of the Act and the regulations at §414.1205 and §414.1210(a), the VM should be applied to assigned claims. However, for non-assigned claims, the limiting charge (the amount that the physician can bill a beneficiary for a non-assigned service) would not be affected if the VM were applied to the claim. This is so, because for non-assigned claims, application of the VM would not affect the limiting charge. Rather, Medicare makes payment for the non-assigned services directly to the beneficiary and the physician receives all payment for a non-assigned service directly from the beneficiary. If the VM were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the VM is positive and decreased when the VM is negative. The application of the VM to non-assigned claims would therefore directly affect beneficiaries and not physicians, contrary to our intent as discussed in previous rulemaking (77 FR 69309). On that basis, we proposed to clarify that we

would apply the VM only to assigned services and not to non-assigned services starting in CY 2015 (79 FR 40504). We do not expect this proposed clarification, to not apply the VM to non-assigned claims, would be likely to affect a physician's decision to participate in Medicare or to otherwise accept assignment for a particular claim. This is because the amount that a provider is entitled to receive from the beneficiary for non-assigned claims is not affected by whether or not the VM is applicable to non-assigned claims. Additionally, to the extent our proposal to expand application of the VM to nonphysician eligible professionals is finalized, we would likewise apply the VM only to services billed on an assignment-related basis and not to non-assigned services. We invited comments on this proposed clarification.

The following is summary of the comments we received on this proposed clarification.

Comment: We received relatively few comments on this technical issue. For those that did comment, nearly all agreed with the proposed clarification and agreed it is important that beneficiary cost-sharing not be affected by the VM, and that the VM should be applied to the amount that Medicare pays to physicians. Some commenters requested a similar policy be applied to the payment adjustments for PQRS and EHR Meaningful Use. A commenter opposed the proposed clarification, encouraging CMS to support non-participating providers by applying the value modifier adjustment to non-assigned claims at the group practice level (TIN), and to evaluate alternative solutions to paying providers other than at the claim level.

Response: We appreciate receiving the comments that supported this technical clarification. However, we are unable to agree with the commenter that suggested an alternative approach to apply the VM to claims submitted by non-participating physicians. As explained above and in the proposal, the application of the VM to non-assigned claims by non-participating physicians would directly affect beneficiaries and not physicians, contrary to our intent. However, we further clarify that the VM will apply to all assigned claims, including those

submitted by both participating and non-participating physicians, and nonphysician eligible professionals to the extent the VM is applied to them. Therefore, the VM will affect non-participating physicians to the extent that they submit assigned claims.

With regard to the comment that a similar policy for non-assigned claims be applied to the PQRS and EHR meaningful use adjustments, we believe the comment is outside of the scope of the proposed rule, although we note that the VM is quite different from the PQRS and EHR-meaningful use adjustments, which apply to the Medicare allowed amount rather than the Medicare paid amount.

After considering the public comments, we are finalizing the proposed clarification to not apply the VM to non-assigned claims for non-participating physicians, and nonphysician eligible professionals to the extent the VM is applied to them.

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 eligible professional services paid under the Medicare PFS will not change as a result of application of the VM.

In the CY 2014 PFS final rule with comment period (78 FR 74770-74771), we adopted a policy to apply a maximum downward adjustment of -2.0 percent for the CY 2016 VM for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are in Category 1 and are classified as low quality/high cost groups.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of -1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323-24). Although we received comments suggesting that larger payment adjustments (both upward and downward) would be necessary to more strongly encourage quality improvements, we finalized our proposed adjustments as we believed they better aligned with our goal to gradually phase in the VM. However, we noted that as we gained experience with our VM methodologies we would likely consider ways to increase the amount of payment at risk, as suggested by some commenters (77 FR 69324).

We believe that we can increase the amount of payment at risk because we can reliably apply the VM to groups with two or more eligible professionals and to solo practitioners in CY 2017 as discussed in section III.N.4.a of this final rule with comment period. Therefore, we proposed to increase the downward adjustment under the VM by doubling the amount of payment at risk from -2.0 percent in CY 2016 to -4.0 percent in CY 2017 (79 FR 40505-40506). That is, for CY 2017, we proposed to apply a -4.0 percent VM to groups with two or more eligible professionals and solo practitioners that fall in Category 2. In addition, we proposed to increase the maximum downward adjustment under the quality-tiering methodology in CY 2017 to -4.0 percent for groups and solo practitioners classified as low quality/high cost and to set the adjustment to -2.0 percent for groups and solo practitioners classified as either low quality/average cost or average quality/high cost. However, as discussed in section III.N.4.c of this final rule with comment period, we proposed to hold solo practitioners and groups with two to nine eligible professionals that are in Category 1 harmless from any downward adjustments under the quality-tiering methodology in CY 2017. Consistent with our previous policy, we note that the estimated funds derived from the application of the downward adjustments to groups and

solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for VM upward payment adjustments. Accordingly, we also proposed to increase the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups and solo practitioners classified as high quality/low cost and to set the adjustment to +2.0x for groups and solo practitioners classified as either average quality/low cost or high quality/average cost (79 FR 40505). We also proposed to continue to provide an additional upward payment adjustment of +1.0x to groups and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). Lastly, we proposed to revise §414.1270 and §414.1275(c) and (d) to reflect the changes to the payment adjustments under the VM for the CY 2017 payment adjustment period. Table 87 shows the proposed quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance). We believe that the VM amount differentiates between cost and quality-tiers in a more meaningful way. We solicited comments on all of these proposals.

TABLE 87: Proposed CY 2017 VM Payment Adjustment Amounts

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 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.

The following is summary of the comments we received on all these proposals.

Comment: The majority of the comments were opposed to our proposals to increase the downward payment adjustments from CY 2016 to CY 2017 for groups and solo practitioners that fall in Category 2 and those that are low quality/high cost under the quality-tiering methodology to -4.0 percent. Commenters expressed their belief that the changes are aggressive. Several commenters indicated that CY 2017 will be the first year that many physicians and all

nonphysician eligible professionals will be subject to the VM, and therefore, recommended maintaining the maximum downward payment adjustment at -2.0 percent for Category 2 and those that are low quality/high cost under the quality-tiering methodology. Commenters indicated that many of these groups and solo practitioners have not yet received their QRURs; therefore, it would be premature to raise the adjustment amount until all groups and solo practitioners have applicable cost and quality metrics and have had an opportunity to participate in the PQRS and VM programs. Commenters indicated that CMS should not increase the amount of payment at risk under quality-tiering and for Category 2 without providing an opportunity for both providers and CMS to understand the implications of the current policies as no group has had experience with the VM since it will be implemented in CY 2015. Other commenters suggested that groups and solo practitioners will have little time to fully understand their baseline performance under the VM. They suggested by delaying the increase of the maximum penalty, CMS would gain experience with applying the VM to a broader variety of groups, and that groups and solo practitioners would increase their understanding of the methodology used to calculate the VM and review their QRURs. Few commenters suggested that if CMS is concerned about PQRS reporting, then it should separate the amount at risk for not reporting under the PQRS (Category 2) from the amount at risk under quality-tiering (Category 1) and that these adjustments should not be at the same level.

Other commenters noted that the cumulative impact of penalties for PQRS, EHR, and the VM would add up to a potential -9.0 percent adjustment to Medicare payments and expressed that this cumulative impact would be overly burdensome. One commenter indicated that the proposed changes would occur in a post-sequester payment environment where providers already experience a -2.0 percent reduction in Medicare payment. Some commenters indicated it was unfair to hold solo practitioners and groups with two to nine eligible professionals at -4.0 percent

for the first year of the VM when groups with of 10 to 99 eligible professionals and groups with 100 or more eligible professionals EPs were at risk for only -2.0 percent and -1.0 percent respectively in their first year of the VM. These commenters suggested that we reduce their Category 2 downward payment adjustment for groups and solo practitioners during their first year in the VM.

By contrast, some supported all of our VM payment adjustment proposals and expressed their belief that a -4.0 percent downward adjustment and +4.0x upward adjustment factor was not sufficient to incentivize physicians to improve quality. A few of these commenters suggested that the amount at risk should eventually be approximately 10.0 percent and that CMS should create a plan in the final rule to continually increase the weight of the VM over time. One commenter noted that there is evidence in the private sector that higher incentives and penalties have a great impact on quality improvement.

Response: We acknowledge the commenters' concerns about doubling the amount of payment at risk from -2.0 percent in CY 2016 to -4.0 percent in CY 2017 under the VM. However, the literature documents a positive correlation between physician participation in quality improvement activities and the extent of the payment adjustment.[22] We agree with the commenters who suggested that smaller groups should be subject to a more gradual phase-in of the VM's application to them, consistent with the experience of the larger groups. We acknowledge that our proposal would have held solo practitioners and groups with two to nine eligible professionals in Category 2 at risk for up to a -4.0 percent payment adjustment for the first year of the VM when groups with of 10 to 99 eligible professionals and groups with 100 or more eligible professionals EPs were at risk for only -2.0 percent and -1.0 percent respectively in

[22] Francois S. de Brantes & B. Guy D'Andrea. Physicians Respond to Pay-for-Performance Incentives: Larger Incentives Yield Greater Participation. Am. J. of Managed Care. 2009. 15,305-310. With regard to hospital participation, this correlation has been documented. Rachel M. Werner, et al. The Effect of Pay-For-Performance In Hospitals: Lessons for Quality Improvement. Health Affairs. 2011. 30,690-698.

the first year that the VM applied to them. In light of these comments, we agree that a smaller increase in the maximum amount of payment at risk for groups with two to nine eligible professionals and solo practitioners would be consistent with our stated focus on gradual implementation and would allow small groups and solo practitioners to gain more experience with the QRURs and the application of the VM. Therefore, we are finalizing -2.0 percent as the maximum amount of payment at risk in CY 2017 for groups with two to nine eligible professionals and solo practitioners. Specifically, in CY 2017, for groups with two to nine eligible professionals and solo practitioners, we will apply a -2.0 percent VM to a group or solo practitioner that falls in Category 2. We note that, as discussed in section III.N.4.c of this final rule with comment period, we are finalizing our proposal to hold solo practitioners and groups with two to nine eligible professionals that are in Category 1 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. Additionally, for groups with two to nine eligible professionals and solo practitioners, we are finalizing a policy to set the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +2.0x if a group or solo practitioner is classified as high quality/low cost and set the adjustment to +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. Table 88 shows the final quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance) for groups with two to nine eligible professionals and solo practitioners.

For groups with ten or more eligible professionals, we are finalizing the payment adjustments as proposed for CY 2017 (79 FR 40505-40506). As stated in the proposed rule (79 FR 40505), we believe that we can increase the amount of payment at risk because groups of this size will have had sufficient experience with the VM prior to the CY 2017 payment adjustment period. By CY 2017, groups with 10 or more eligible professionals will have had at least one

year experience under the VM program. As stated in the CY 2014 PFS final rule with comment period (78 FR 74769), on September 16, 2013, we made available to all groups of 25 or more eligible professionals an annual QRUR based on 2012 data to help groups estimate their quality and cost composites. As discussed in section III.N.4.a. of this final rule with comment period, in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. We believe that groups of 10 or more eligible professionals will have had adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2017. As a result, we believe it is appropriate to increase the amount of payment at risk for groups with ten or more eligible professionals in CY 2017.

Consequently, for CY 2017, we will apply a -4.0 percent VM to groups with ten or more eligible professionals that fall in Category 2. In addition, we will set the maximum downward adjustment under the quality-tiering methodology in CY 2017 to -4.0 percent for groups with ten or more eligible professionals classified as low quality/high cost and set the adjustment to -2.0 percent for groups with ten or more eligible professionals 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 2017 to +4.0x for groups with ten or more eligible professionals classified as high quality/low cost and set the adjustment to +2.0x for groups with ten or more eligible professionals classified as either average quality/low cost or high quality/average cost. Table 89 shows the final quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance) for groups with ten or more eligible professionals.

We are also finalizing our proposal to continue to provide an additional upward payment adjustment of +1.0x to groups with two or more eligible professionals and solo practitioners that

care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). Lastly, we are finalizing the revisions at §414.1270(c) and §414.1275(c) and (d) to reflect the payment adjustments under the VM for the CY 2017 payment adjustment period. Tables 88 and 89 show the quality-tiering payment adjustment amounts for CY 2017 (based on CY 2015 performance). We believe that these final policies will alleviate commenters' concern that our proposals were too aggressive for smaller groups and solo practitioners that are new to the VM in CY 2017, while continuing the gradual phase-in of the VM for groups with ten or more eligible professionals with an emphasis on the importance of reporting under the PQRS program and improving the quality and efficiency of services provided to Medicare beneficiaries.

TABLE 88: Final CY 2017 VM Payment Adjustment Amounts for Groups with Two to Nine Eligible Professionals and Solo Practitioners

Cost/Quality	Low quality	Average quality	High quality
Low cost	+0.0%	+1.0x*	+2.0x*
Average cost	+0.0%	+0.0%	+1.0x*
High cost	+0.0%	+0.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 89: Final CY 2017 VM Payment Adjustment Amounts for Groups with Ten 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 measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), the upward payment adjustment factor ("x" in Tables 88 and 89)

will be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We noted in the proposed rule 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 VM upward payment adjustments (79 FR 40504).

In section III.N.4.d of the proposed rule (79 FR 40506), we discussed our proposal to apply the VM to physicians in groups with two or more eligible professionals and to physicians who are solo practitioners that participate in the Shared Savings Program during the payment adjustment period beginning with the CY 2017 payment adjustment period. We noted in the CY 2015 PFS proposed rule that will have the final list of ACOs that will participate in the Shared Savings Program during the payment adjustment period and their participant TINs during the late fall prior to the beginning of the payment adjustment period (for example, the late fall of CY 2016 prior to the CY 2017 payment adjustment period) (79 FR 40506). We also noted that this final list may not be available until after the beginning of the payment adjustment period. Therefore, we proposed to calculate preliminary payment adjustment factors ("x" in Table 87) prior to the beginning of the payment adjustment period, and subsequently finalize the payment adjustment factors after the final ACO participation list is completed. We note that the final payment adjustment factors may be updated depending on the outcome of the informal inquiry process described later at section III.N.4.i of this final rule with comment period.

We did not receive any comments on these proposals.

As discussed in section III.N.4.d of this final rule with comment period, we are finalizing a policy to use the performance period to determine which groups and solo practitioners participate in the Shared Savings Program for purposes of calculating their VM in CY 2017. Therefore, we are not finalizing our proposal to calculate preliminary payment adjustment

factors ("x" in Tables 88 and 89) prior to the beginning of the payment adjustment period, and then recalculating the payment adjustment factors after the final ACO participation list is completed. However, we are finalizing our proposal that we may update the payment adjustment factors, depending on the outcome of the informal inquiry process described later at section III.N.4.i of this final rule with comment period.

g. Performance Period

In the CY 2014 PFS final rule with comment period (78 FR 74771 through 74772), we adopted a policy that performance on quality and cost measures in CY 2015 will be used to calculate the VM that is applied to items and services for which payment is made under the PFS during CY 2017. Accordingly, we added a new paragraph (c) to §414.1215 to indicate that the performance period is CY 2015 for VM adjustments made in the CY 2017 payment adjustment period.

h. Quality Measures

In the CY 2014 PFS final rule with comment period (78 FR 74773), we aligned our policies for the VM for CY 2016 with the PQRS group reporting mechanisms available to groups in CY 2014 and the PQRS reporting mechanisms available to individual eligible professionals in CY 2014, such that data that groups submit for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2014 and the data that individual eligible professionals submit through any of the individual PQRS reporting mechanisms in CY 2014 will be used for calculating the quality composite under the quality-tiering approach for the VM for CY 2016. Moreover, all of the quality measures for which groups and individual eligible professionals are eligible to report under the PQRS in CY 2014 would be used to calculate the VM for a group for CY 2016 to the extent the group or individual eligible professionals in the group submits data on such measure in accordance with our 50 percent threshold policy (78 FR

74768). We also noted that, in accordance with 42 CFR 414.1230, three additional quality measures (outcome measures) for groups subject to the VM will continue to be included in the quality measures used for the VM in CY 2016. These measures are: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

PQRS Reporting Mechanisms: It is important to continue to align the VM for CY 2017 with the requirements of the PQRS, because quality reporting is a necessary component of quality improvement. We also seek not to place an undue burden on eligible professionals to report such data. Accordingly, for purposes of the VM for CY 2017, 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 2015 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2015. These reporting mechanisms were described in Tables 21 through 49 of the proposed rule (79 FR 40404).

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 2017 to the extent that a group (or individual eligible professionals in the group, in the case of the "50 percent option") or solo practitioner submits data on these measures. These PQRS quality measures were described in Tables 21 through 49 of the proposed rule (79 FR 40404).

We proposed that groups with two or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey

for CY 2015 in their VM for CY 2017 (79 FR 40506). We also proposed to continue to include the three outcome measures in §414.1230 in the quality measures used for the VM in CY 2017. For groups that are assessed under the "50 percent option" for the CY 2017 VM, we proposed to calculate the group's performance rate for each measure reported by at least one eligible professional in the group by combining the weighted average of the performance rates of those eligible professionals reporting the measure. We also proposed for groups that are assessed under the "50 percent option" for the CY 2017 VM to classify a group's quality composite score as ''average'' under the quality-tiering methodology, if all of the eligible professionals in the group satisfactorily participate in a PQRS qualified clinical data registry in CY 2015 and we are unable to receive quality performance data for those eligible professionals. We wish to clarify that in this proposal, the phrase "all of the eligible professionals in the group" refers to the at least 50 percent of eligible professionals in the group who report as individuals under PQRS. In other words, we proposed for groups that are assessed under the "50 percent option" for the CY 2017 VM, where all of the eligible professionals in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS qualified clinical data registry in CY 2015, and we are unable to receive quality performance data for those eligible professionals, then we would classify the group's quality composite score as ''average'' under the quality-tiering methodology. If some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, we would calculate the group's score based on the reported performance data that we obtain through those other mechanisms (79 FR 40507).

Although we finalized policies in the CY 2014 final rule with comment period that would allow groups assessed under the "50 percent option" to have data reported through a PQRS qualified clinical data registry in CY 2014 used for the purposes of their CY 2016 VM to the

extent performance data are available, we noted that we did not directly address the issue of how we would compute the national benchmarks for these measures. Under §414.1250, benchmarks for the quality of care measures for the VM are the national mean performance rate for a measure during the year prior to the performance period. In the CY 2013 PFS final rule (77 FR 69322), we finalized a policy that if a measure is new to the PQRS, we will be unable to calculate a benchmark and performance on that measure will therefore not be included in the quality composite. Consistent with these existing policies, we proposed to not include in the VM quality composite those measures reported through a PQRS qualified clinical data registry that are new to PQRS (in other words, measures that were not previously reported in PQRS) (79 FR 40507). This policy would apply beginning with the measures reported through a PQRS qualified clinical data registry in the CY 2014 performance period for the CY 2016 payment adjustment period. We welcomed public comment on this proposal.

We noted that the PQRS administrative claims option described in §414.1230, is no longer available through PQRS (79 FR 40507). However, we are clarifying that the three claims-based outcome measures described in §414.1230, are still used in calculating the quality composite for purposes of the VM. We proposed to clarify that we calculate benchmarks for those outcome measures described in §414.1230 using the national mean for a measure's performance rate during the year prior to the performance period in accordance with our regulation at §414.1250(b) (79 FR 40507). We welcomed public comment on this proposal.

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

Comment: Several commenters supported the alignment of VM with PQRS requirements. Other commenters, however, raised concerns about the lack of applicable quality measures for multiple specialties and nonphysician eligible professionals, which they believe could result in an automatic downward payment adjustment for professionals who are unable to report. Several

commenters also suggested CMS should include measures in the VM only after physicians had reported on the measures under PQRS for at least a year. Several commenters supported our proposal to continue our existing VM benchmarking policy for measures that are new to PQRS or reported via a Qualified Clinical Data Registry (QCDR). Several commenters supported our proposal to allow optional reporting of patient experience of care measures for groups of two or more physicians. However several commenters urged us to consider additional patient experience measures that are relevant to beneficiaries using specific Medicare benefits. One commenter suggested that CAHPS data should be collected throughout the year, allowing providers to prioritize and monitor the effectiveness of improvement efforts, especially as patient experience of care data will be incorporated into the VM in CY 2017. One commenter suggested that the patient experience of care measures should be optional for quality tiering for the CY 2017 VM, as the 2013 GPRO web participants are still awaiting the results of the survey administration. A number of commenters stated that CMS should not make patient experience measures a required component of the VM in the future.

Response: PQRS measures are highly reliable measures for understanding the health and functional status of beneficiaries after treatment by a participating group or solo practitioner.[23] In previous rulemakings we have committed to expanding the specialty measures available in PQRS in order to more accurately measure the performance on quality of care furnished by specialists and we reaffirm our commitment to using measures of performance across specialties that are reliable and valid for the VM program (77 FR 69315; 78 FR 74773). Moreover, we believe group reporting can ameliorate the commenters' concerns that the current set of PQRS measures does not capture all of the clinical care that some specialists and sub-specialists

[23] Mathematica Policy Research, "Experience Report for the Performance Year 2012 Quality and Resource Use Reports." (January 8, 2014).

furnish. We also continue to believe that alignment with the PQRS program is an important goal for the VM, because it minimizes burden on providers and encourages widespread participation in quality reporting.

As we stated in section III.N.4.a of this final rule with comment period, where a group or solo practitioner falls in Category 1 under the VM (that is, meets the criteria to avoid the CY 2017 PQRS payment adjustment), but the group or solo practitioner does not have at least 20 cases for each PQRS measure on which it reports as required for inclusion in the quality composite of the VM, the group or solo practitioner's quality composite score would be based on the three claims-based outcome measures described at §414.1230, provided that the group or solo practitioner has at least 20 cases for at least one of the claims-based outcome measures. As discussed in section III.N.4.h of this final rule with comment period, eligible professionals and groups concerned about the lack of specialty measures to meet PQRS reporting requirements should note that PQRS has a Measure Applicability Validation (MAV) process. MAV determines PQRS incentive eligibility for eligible professionals and groups reporting less than nine measures across three domains or nine or more across less than three domains. We recommend that commenters refer to the Measure Application Validation (MAV) Process to alleviate concerns that lack of applicable measures would result in an automatic downward adjustment under the VM . http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Claims_MeasureApplicabilityValidation_12132013.zip. Also, please refer to section III.K.2 of this final rule with comment period for the final 2017 policies for MAV and the criteria for satisfactory reporting for the 2017 PQRS payment adjustment.

With regard to the commenters' suggestion that the VM should include only measures on

which physicians have reported under PQRS for at least one year, we note that we are maintaining the policy set forth in §414.1250 that benchmarks for the quality of care measures are the national mean of a measure's performance rate during the year prior to the performance period. Measures reported through a PQRS qualified clinical data registry 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. We acknowledge the interest in ensuring that physicians report on measures for at least one year before they are included in the VM. Our current policy achieves that end by precluding the use of measures for which no benchmarking data is available.
We acknowledge the comments suggesting that CMS expand the data collected on the patient experience of care (CAHPS) measures and note that we seek to align with the PQRS program in order to minimize reporting burden and align incentives across CMS incentive payment programs. We will consider these suggestions for any future refinements to the patient experience measures included in the PQRS program and the VM. CMS will provide survey results and post benchmarks for the patient experience of care measures; this data as well as the survey questions that can be accessed on the CMS website can be utilized to prioritize performance improvement efforts. We also acknowledge the commenters' concerns with expansion of mandatory CAHPS inclusion in the VM and note that we would propose any such policy change through future notice and comment rulemaking.

After consideration of the comments, 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 2017, to the extent that a group (or individual eligible professionals in the group, in the case of the "50 percent option") or solo practitioner submits data on these measures. We are finalizing our policy that groups with two or more eligible professionals can elect to include the patient experience of care measures

collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We are finalizing our policy to continue to include the three outcome measures in §414.1230 in the quality measures used for the VM in CY 2017. We are finalizing our policy that for groups that are assessed under the "50 percent option" for the CY 2017 VM, we will calculate the group's performance rate for each measure reported by at least one eligible professional in the group by combining the weighted average of the performance rates of those eligible professionals reporting the measure.

We are finalizing our policy at §414.1270(c)(4) that, for groups that are assessed under the "50 percent option" for the CY 2017 VM, where all of the eligible professionals in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS qualified clinical data registry in CY 2015, and we are unable to receive quality performance data for those eligible professionals, then we will classify the group's quality composite score as ''average'' under the quality-tiering methodology. Because this is the same policy as for the CY 2016 payment adjustment period, we are also making a conforming revision to §414.1270(b)(4).

We are finalizing a policy that, for groups that are assessed under the "50 percent option" where some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, then we will calculate the group's score based on the reported performance data that we obtain through those other PQRS reporting mechanisms. We are finalizing a policy that, beginning with the CY 2014 performance period, measures reported through a PQRS qualified clinical data registry that are new to PQRS will not be included in the quality composite for the VM until such time as we have historical data to calculate benchmarks for them. Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure's performance rate during the

year prior to the performance period (§414.1250). We are finalizing our proposed clarification that we calculate benchmarks for the outcome measures described in §414.1230 using the national mean for a measure's performance rate during the year prior to the performance period in accordance with our regulation at §414.1250(b). Although we did not include proposed regulation text for this proposed clarification of our policy, we are finalizing revisions to regulation text at 414.1250(b) to reflect this final policy.

Quality Measures for the Shared Savings Program: Starting with the CY 2017 payment adjustment period, as described in section III.M. of this final rule with comment period , we proposed to apply the value modifier to groups and solo practitioners participating in ACOs under the Shared Savings Program. To do so, we proposed quality measures and benchmarks for use with these groups and solo practitioners and solicited public comment on these proposals. We describe these proposals more fully below.

With regard to quality measures, we noted that there is substantial overlap between those used to evaluate the ACOs under the Shared Savings Program and those used in the PQRS program and for the value modifier payment adjustment. For the CY 2017 payment adjustment period and subsequent payment adjustment periods, to determine a quality composite for the VM for groups and solo practitioners who participate in an ACO under the Shared Savings Program, we proposed to use the quality measures that are identical for the two programs. Specifically, for the CY 2017 payment adjustment period, we proposed to use the PQRS GPRO Web Interface measures and the outcome measure described at §414.1230(c) to determine a quality composite for groups and solo practitioners who participate in an ACO under the Shared Savings Program. Because the ACO GPRO Web Interface measures and PQRS GPRO Web Interface measures will be the same in CY 2015, we proposed to use the GPRO Web Interface measures reported by ACOs in determining the quality composite for groups and solo practitioners participating in

ACOs under the Shared Savings Program in CY 2017 (79 FR 40507). Utilizing these GPRO Web Interface measures in this regard further encourages successful quality reporting for Shared Savings Program ACOs. Additionally, we stated our belief that the all-cause hospital readmissions measure as calculated for ACOs under the Shared Savings Program is equivalent to the all-cause hospital readmissions measure we have adopted for the VM at §414.1230(c), and therefore, proposed use of that measure as calculated for ACOs in the Shared Savings Program for inclusion in the VM for the CY 2017 payment adjustment period (79 FR 40507). We note that the outcome measures described at §414.1230(a) and §414.1230(b) are not currently calculated for ACOs in the Shared Savings Program. These measures are: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; and (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia. Because we have no experience with these measures in the Shared Savings Program, at this time, we did not propose to include these measures for groups and solo practitioners who participate in ACOs under that program. We proposed to modify the regulations at §412.1210 accordingly.

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

Comment: The majority of commenters opposed the proposals for two reasons. First, these commenters expressed their belief that the ACO would be required to report measures twice or report additional measures. Second, these commenters suggested that aligning the measures used in the Shared Savings Program and those in the VM program could lead to ACOs scoring well in one program while performing poorly in the other. Commenters believe that the VM and Shared Savings Program use different performance benchmarks and different approaches for determining good versus bad performance.

A few medical societies supported the proposals, recognizing CMS's intent to align the measures and quality improvement goals of the Shared Savings Program and VM program. Several commenters suggested allowing groups that are new to GPRO Web Interface reporting to have at least one year to report measures before they are measured for performance. A few commenters recommended aligning the Shared Savings and the VM programs by removing the three claims-based outcome measures from the VM.

Response: We disagree with the commenters' suggestion that utilizing GPRO Web Interface measures to calculate Shared Savings Program ACO's quality composites would cause them additional reporting burden, because the ACO GPRO Web-Interface measures and PQRS GPRO Web-Interface measures are the same. We believe, therefore, that utilizing the GPRO web interface measures for Shared Savings Program ACO quality composite calculation under the VM will further encourage successful quality reporting for ACOs in the Shared Savings Program and will not add burdensome reporting requirements. ACOs in the Shared Savings Program would not have to report measures twice for purposes of the VM. Moreover, the use of the GPRO Web Interface measures fosters alignment among the various CMS quality reporting programs. With regard to commenters' suggestion that Shared Savings Program ACO participants might fare well on measures reported under the Shared Savings Program and poorly under the VM program, we do not believe this situation is likely to occur, because within the Shared Savings Program, ACOs will be measured against national benchmarks that are calculated using Medicare fee-for service data. The VM program also develops benchmarks using all available Medicare fee-for-service data. Although the benchmarking methodology differs in that the VM uses a national weighted mean and the Shared Savings Program use a decile distribution for measuring performance, we believe using the same data source enables a fair comparison for all groups and solo practitioners subject to the value modifier.

Further, we believe it is appropriate to use the Shared Savings Program ACOs' all-cause readmission measure for calculating the VM for the CY 2017 payment adjustment period. As we stated in the proposed rule, we believe that the Shared Savings Program ACO all-cause readmission measure is equivalent to the all-cause hospital readmission measure adopted for the VM. The use of this measure will not impose any additional reporting burden on Shared Savings Program ACOs (79 FR 40508).

After considering the public comments, we are finalizing a policy to use the ACO Group Practice Reporting Option (GRPO) 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.

To determine the standardized scores for these quality measures for use with those participating in ACOs under the Shared Savings Program, we proposed to apply the benchmark policy for quality measures for the VM as described under §414.1250. Under this policy, the VM benchmarks are the national mean for a measure's performance rate based on data from one year prior to the performance period. We believe these are the appropriate benchmarks to use when determining the value modifier payment adjustment because they are the same benchmarks used to determine the value modifier payment adjustment for other groups and solo practitioners and they are similar to the benchmarks used under the Shared Savings Program. As stated above, within the Shared Savings Program, ACOs will be measured against national benchmarks that are calculated using Medicare fee-for service data and the VM program also develops benchmarks using all available Medicare fee-for-service data., We believe that use of the VM benchmarks creates a reasonable comparison among groups and solo practitioners and it is appropriate to evaluate those that participate in Shared Savings Program ACOs on the same basis as those that do not participate in the Shared Savings Program for the purpose of the value

modifier. We believe that the VM benchmarks are appropriate because they include all PQRS data available (77 FR 69322), including quality data used for the Shared Savings Program. . We stated that , while the Shared Savings Program develops benchmarks using all available Medicare fee-for-service data, we do not believe it is appropriate to use benchmarks from the Shared Savings Program to determine standardized scores for the quality composite of the value modifier payment adjustment. We do not think this enables a fair comparison among groups and solo practitioners subject to the value modifier because the Shared Savings Program benchmarks use gradients by decile (including the median) of national performance based on data two years prior to the performance period (78 FR 74759 through 74760).

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

Comment: A number of commenters opposed the proposal for the following reasons: the belief that a difference in performance benchmarks for the VM and Shared Savings Program could cause ACOs to score well in one program and perform poorly in the other; and the belief that the application of the VM benchmarking policy to the quality measures used by ACOs under the Shared Savings Program could introduce potential bias into the broader VM program. One commenter supported our proposal, noting that alignment of quality measures for the VM and Shared Savings Program would strengthen the benchmarks by establishing a larger pool of providers with comparable measures.

Response: We appreciated the comments received. As stated above, with regard to the suggestion that Shared Savings Program ACO participants might fare well on measures reported under the Shared Savings Program and poorly under the VM program, we do not believe this situation is likely to occur, because the GPRO Web Interface measures used for the Shared Savings Program ACOs and the VM are the same and benchmarks used for performance measurement on use the same data source (fee-for-service Medicare data). We also do not

believe that introduction of SSP ACO data into the benchmarks would create a bias. We utilize national data for benchmarking, and we agree with the commenter who stated that this will strengthen the benchmarks by expanding the pool of participants. After consideration of the public comments received, we are finalizing the proposal to apply the benchmark policy 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.

All-Cause Hospital Readmissions Measure: We finalized the inclusion of the all-cause hospital readmissions measure described at §414.1230(c) in the CY 2013 PFS final rule with comment (77 FR 69285). We subsequently investigated the reliability of this measure. We also have an existing policy at §414.1265, that a claims-based cost or quality measure must have a minimum of 20 cases, to be included in a composite score calculation. Furthermore, according to §414.1265(a), if a group has fewer than 20 cases for a measure in a performance period, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

Based on 2012 data, we found that the average reliability for the all-cause hospital readmissions measure was below 0.4 when we examined groups with fewer than 200 cases but exceeded 0.4 for groups with 200 or more cases. Although we do not believe there is a universal consensus concerning a minimum reliability threshold, reliability scores in the 0.4 to 0.7 range are often considered moderate, and scores greater than 0.7 are considered high. In general, we found that the groups with at least 10 eligible professionals were more likely to have 200 or more cases as compared to groups with fewer eligible professionals. Thirty percent of groups with 10 or more eligible professionals had 200 or more cases, as compared to 3 percent of groups with 1-

9 eligible professionals. We found that the average reliability exceeded 0.4 for groups of all sizes (1 or more eligible professionals), with 200 or more cases. .

After examining the reliability of the all-cause hospital readmissions measure data for 2012 across all group sizes and considering its impacts on the cost composite of the VM as discussed below, we proposed to change the reliability policy (minimum number of cases) with respect to this measure. Specifically, beginning with the CY 2017 payment adjustment period, we proposed to change the reliability policy (minimum number of cases) with respect to the all-cause hospital readmissions measure as described in §414.1230(c) from a minimum of 20 cases to a minimum of 200 cases for this measure to be included in the quality composite for the VM. For this measure only, we proposed to exclude the measure from the quality domain for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period. In implementing this proposal, we noted that we would only apply it to the all-cause hospital readmissions measure as it is calculated for groups or solo practitioners who are not part of a Shared Savings Program ACO. In instances where we are including Shared Savings Program data for groups or solo practitioners who are part of a Shared Savings Program ACO, we would include their all-cause hospital readmissions measure as it is calculated for the Shared Savings Program. This approach to implementing this proposal is appropriate because the Shared Savings Program has taken into consideration the size of its groups in finalizing inclusion of this measure, and we value consistency with the Shared Savings Program's reporting requirements for its participants, to the extent it is practicable. We would continue to include the measure in the VM quality domain for groups or solo practitioners who have 200 or more cases. We proposed to modify §414.1265 to reflect this proposal. We welcomed comments on this proposal.

We noted that, if we were to revise the minimum case size for the all-cause hospital readmissions measure for the quality composite of the VM, poor performance on controlling readmissions would continue to have an effect on the VM for groups with between 20 and 199 cases through the cost composite of the VM. The Medicare Spending per Beneficiary (MSPB) measure, as finalized in the CY 2014 PFS final rule (78 FR 74775-74780), is a measure of all Medicare Part A and Part B payments during an episode spanning from 3 days prior to an index hospital admission through 30 days post-discharge with certain exclusions. Since all Part A and Part B spending is included in the 30 day post-discharge window, Medicare Part A payments for a readmission that are included in an MSPB episode will increase the MSPB amount relative to an MSPB episode without a readmission in the 30-day post-discharge window. Additionally, the cost of readmissions is incorporated as part of the 5 total per capita cost measures that comprise the remainder of the cost composite of the VM. The 5 total per capita cost measures are annual measures that include the costs of all Part A and Part B spending during the year, including the costs of readmissions. Therefore, readmission costs will have the effect of increasing total per capita cost spending for the groups attributed these patients' costs. As a result, poor performance on controlling readmissions already will have an adverse effect on an attributed group's cost composite of the VM, even if poor performance on the all-cause hospital readmissions measure would no longer be reflected in certain groups' or solo practitioners' quality composite of the VM due to having fewer than 200 all-cause hospital readmission cases. Even for those groups for which the all-cause hospital readmissions measure would be excluded from the quality composite calculations, groups would continue to have incentive to control readmissions, since doing so would reduce readmission costs, thereby improving performance on the payment-standardized, risk-adjusted cost measures used for the cost composite of the VM.

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

Comment: We received few comments on this proposal. Some commenters supported the inclusion of the all-cause readmission measure. One commenter supported the proposed change in the reliability policy for the hospital all-cause readmission measure, stating that this will provide valid and reliable estimates for hospital admissions to each group. Several commenters supported the need for reliable measures; however, one commenter expressed concern that even with an increased case minimum, the all-cause readmission measure was still not appropriate for physician accountability because the readmission costs are already included in the total per capita costs, the measure was not specified for group level measurement, and the measure was not supported by the Measures Application Partnership (MAP). This commenter stated that the all-cause readmission measure does not add value to the VM, further suggesting that if CMS chooses to keep the measure, then it should be adjusted for clinical and socioeconomic factors. Another commenter recommended CMS undertake an analysis to ensure this change would not result in disproportionate penalties for certain groups (such as surgeons) prior to finalizing this proposal.

One commenter stated that this measure is not appropriate for physician practices because 2012 data indicates that the measure could not meet a 0.4 percent reliability threshold at a 20-case minimum. This commenter also questioned the justification for including a measure that will be applicable only to 30 percent of groups with 10 or more practitioners and three percent of smaller groups, even when the proposed minimum 200 case threshold is utilized.

Response: We disagree with the commenters' assessment of the reliability of the all-cause hospital readmission measure, which quantifies the unplanned readmissions for any cause within 30 days from the date of discharge of an index admission. Our analysis of this measure based on 2012 data found that the average reliability exceeded 0.4 for groups with 200 or more cases included all group sizes (1 or more eligible professionals). We are committed to

monitoring this measure, as well as others to ensure that the minimum patient panel size is sufficient to meet the reliability standard for the VM program. With regard to concern that readmission costs are included in other spending measures, we disagree that this fact makes the all-cause hospital readmissions measure inappropriate for inclusion in the VM. The all-cause hospital readmissions measure is a measure of readmission rates, not of costs and we believe that readmission reduction is an important goal that we can emphasize through the VM. We note that the measure's direction was supported by the MAP and also that the has been specified for groups. The group specifications may be found at: http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-8.pdf

With regard to commenters' concerns related to the issue of socioeconomic status adjustment, we continue to monitor activities at the National Quality Forum (NQF), such as the July 23, 2014 decision by the NQF Board in which the Board approved a trial period to test the impact of sociodemographic factor risk adjustment of performance measures (available at http://www.qualityforum.org/Press_Release/2014/NQF_Board_Approves_Trial_Risk_Adjustment.aspx). While we continue to evaluate the appropriateness of applying different standards for the outcomes of patients of low socioeconomic status and the potential for an socioeconomic status adjustment to mask potential disparities or minimize incentives to improve the outcomes of economically disadvantaged populations, we would take any future decision by the NQF on this issue into consideration for any potential future refinements to this or any measure included in the VM.

After consideration of the comments, we are finalizing the policy, beginning with the CY 2017 payment adjustment period, to increase the case minimum from 20 cases to 200 cases for the all-cause hospital readmissions measure as described in §414.1230(c) to be included in the quality composite for the VM as proposed. Therefore, we are finalizing the proposal to exclude

the measure from the quality domain for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period and all remaining measures in the domain will be given equal weight. We are codifying this change with a revision to the regulation at §414.1265.

i. 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; and
- The determination of costs.

These statutory requirements regarding limitations of review are reflected in §414.1280. Despite the preclusion of administrative and judicial review, we previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at §414.1285. We stated that we intend to disseminate reports containing CY 2013 data in the fall of 2014 to

groups of physicians subject to the VM in 2015 and that we will make a help desk available to address questions related to the reports.

We stated it would be appropriate to align with PQRS to consider requests for informal review of whether a group or solo practitioner successfully reported under the PQRS program and requests for reconsideration of PQRS data as described in section III.K, as well as to expand our current informal inquiry process to accept requests from groups and solo practitioners to review and correct certain other errors related to the VM, such as errors made by CMS in assessing the eligibility of a group or solo practitioner for the value modifier based on participation in a Shared Savings Program ACO, the Pioneer ACO Model, the CPC Initiative, or other similar Innovation Center models or CMS initiatives; computing standardized scores; computing domain scores; computing composite scores; or computing outcome or cost measures. We are working to develop and operationalize the necessary infrastructure to support such a corrections process, but at this time, we do not believe we would be able to implement the process until 2016 at the earliest.

Therefore, for the CY 2015 payment adjustment period, to align with PQRS, we proposed to expand the informal inquiry process at §414.1285 to establish an initial corrections process that would allow for some limited corrections to be made (79 FR 40509). Specifically, under this initial corrections process, for the CY 2015 payment adjustment period, we proposed to establish a deadline of January 31, 2015 for a group to request correction of a perceived error made by CMS in the determination of its CY 2015 VM payment adjustment. Alternatively, we solicited comment on a deadline of no later than the end of February 2015 to align with the PQRS informal review process. We would then make a determination regarding the request. At this time, we do not anticipate it would be operationally feasible for us to fully evaluate errors with regard to quality measure data and accept data as described above under section III.K. for

the CY 2015 payment adjustment period, and thus we proposed to classify a TIN as "average quality" in the event we determine that we have made an error in the calculation of quality composite. We proposed to recompute a TIN's cost composite in the event we determine that we have made an error in its calculation. We proposed to adjust a TIN's quality-tier if we make corrections to a TIN's quality and/or cost composites as a result of this initial corrections process. We noted that there would be no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act.

Starting with the CY 2016 payment adjustment period (which has a performance period of CY 2014), we proposed to continue the expanded informal inquiry process at §414.1285 as described above. However, in anticipation of having the necessary operational infrastructure to support the reconsideration of quality measure data, we proposed to establish a 30-day period that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request correction of a perceived error made by CMS in the determination of the group or solo practitioner's VM for that payment adjustment period. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and will show how all TINs would fare under the policies established for the VM for the CY 2015 payment adjustment period. Similar to our proposal for the initial corrections process in CY 2015, we would then make a determination regarding the requests received. Since we anticipate it would be operationally feasible for us to fully evaluate errors with regard to quality measure data at that point, and accept data, consistent with PQRS policies, as described above under section III.K. for the CY 2016 payment adjustment period, we proposed to recompute a TIN's quality composite and/or cost composite in the event we determine that we have made an error in the calculation. We noted that if the operational infrastructure is not available to allow this recomputation, we proposed to continue the approach

of the initial corrections process 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 proposed to adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites as a result of this corrections process.

We welcomed comment on these proposals.

The following is summary of the comments we received on both the initial corrections process in the CY 2015 payment adjustment period and the corrections process we proposed beginning with the CY 2016 payment adjustment period.

Comment: Commenters supported implementing an expanded informal inquiry process to allow for corrections to the VM. However, almost all commenters requested later deadlines for submission of VM corrections. Specifically:

- For 2015, most commenters supported establishing a deadline of no later than the end of February 2015, rather than January 31, to align with the PQRS informal review process.
- For subsequent years, most commenters requested a longer period of 60 to 90 days (rather than 30 days) that would start after the release of the QRURs for the applicable performance period for a group or individual to request a correction of a perceived error related to the VM calculation.

In addition, some commenters objected to the proposal for 2015 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. These commenters believe it would be inappropriate to deem a group "average quality" simply because CMS does not have the capacity to correct its own errors, especially if an "average quality" rating could potentially lead to penalties or lost incentive payments. Some commenters suggested that we consider requests for providers to resubmit their quality data. Other commenters asked that we provide additional clarification regarding

what situations will be considered in the informal review process.

Response: We are persuaded by commenters who request that we establish later deadlines for the VM informal review process so that such deadlines are consistent with those of the PQRS informal review process. We agree with these comments since data reported under PQRS is an important component of the VM and that corrections to PQRS measure rates could affect the calculation of the VM payment adjustment amount. Therefore, for the CY 2015 payment adjustment period, the deadline for submission of a request for VM informal review will be the end of February, 2015. Likewise, for subsequent payment adjustment years, we are persuaded by commenters that requested a longer period beyond 30 days, which would start after the release of the QRURs for the applicable performance period, for a group or individual to request a correction of a perceived error related to the VM calculation. However, we believe that 60 days, not 90 days, would be a sufficient amount of time for providers to access their QRUR reports, review the information, which includes the VM payment adjustment amount that will apply for the subsequent payment adjustment year and make a decision whether or not to submit a VM correction request. Establishing a 60-day deadline enables us to make corrections prior to, or relatively soon after, the start of the applicable payment adjustment year. This helps reduce the number of claims that would need to subsequently be reprocessed during the applicable payment adjustment year.

Finally, as we discussed in the proposal and above, it is not operationally feasible to fully evaluate errors with regard to quality measure data and accept data as described above under section III.K. for the CY 2015 payment adjustment period. Therefore, to minimize the impact on providers, we will classify a TIN as ‘‘average quality’’ in the event that we determine that we have made an error in the calculation of the quality composite. However, we understand the point made by a few commenters about this policy. It is possible that an “average quality” rating

for the CY 2015 payment adjustment period could potentially result in a higher or lower VM payment adjustment amount for an individual TIN than if the quality composite were recalculated. Therefore, we are working to develop the operational infrastructure to allow us to re-compute a TIN's quality composite and accept data, consistent with PQRS quality data resubmission policies, as described above under section III.K. for the CY 2016 payment adjustment period in the event we determine that we have made an error in the calculation.

After consideration of the public comments received:

- For the CY 2015 payment adjustment period, we are: (1) finalizing 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) finalizing 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 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, and (2) we will take steps to establish a process for accepting requests from providers to correct certain errors made by CMS or a third-party vendor (for example, registry). We intend to design this process as a means to re-compute a TIN's quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We note that if the operational infrastructure is not available to allow this re-computation, we will 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.

For both the CY 2015 payment adjustment period and future adjustment periods, we will adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites as a

result of this corrections process. We will provide additional operational details as necessary in sub-regulatory guidance.

We further note 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.

j. Potential Methods to Address NQF Concerns Regarding the Total Per Capita Cost Measures

In the CY 2013 PFS final rule with comment period (77 FR 69322), we established a policy to create a cost composite for each group subject to the VM that includes five payment-standardized and risk-adjusted annual per capita cost measures. To calculate each group's per capita cost measures, we first attribute beneficiaries to the group. We attribute beneficiaries using a two-step attribution methodology that is based on the assignment methodology used for the Shared Savings Program and the PQRS GPRO and that focuses on the delivery of primary care services (77 FR 69320) by both primary care physicians and specialists.

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the Medicare Spending Per Beneficiary (MSPB) measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. As we proposed, we are using the MSPB amount as the measure's performance rate rather than converting it to a ratio as is done under the Hospital Inpatient Quality Reporting (IQR) and VBP Programs. We finalized that the MSPB measure is added to the total per capita costs for all attributed beneficiaries domain and equally weighted with the total per capita cost measure in that domain. Additionally, we finalized that an MSPB episode is attributed to a single group of physicians that provides the plurality of Part B services (as measured by standardized allowed charges) during the index admission, for the purpose of calculating that group's MSPB measure rate. Finally, we finalized a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a physician group's cost composite.

Additionally, in the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized our proposal to use the specialty adjustment method to create the standardized score for each group's cost measures beginning with the CY 2016 VM. That is, we refined our current peer group methodology to account for specialty mix using the specialty adjustment method. We also finalized our proposal to include this policy in our cost composite methodology. Additionally, we finalized our proposal to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims.

As discussed in the CY 2014 PFS final rule with comment period (78 FR 74781), we submitted the total per capita cost measure for National Quality Forum (NQF) endorsement in January 2013. In the final voting in September 2013, the NQF Cost and Resource Use Committee narrowly voted against the measure by a count of 12 in support and 13 in opposition. We proposed to address two of the major concerns that Committee raised in its review of the measure. First, we proposed modifications to our two-step attribution methodology. Second, we proposed to reverse the current exclusion of certain Medicare beneficiaries during the performance period. We stated that these proposals would apply beginning with the CY 2017 payment adjustment period for the VM and would apply to all five of the total per capita cost measures under §414.1235(a)(1) through (5) (79 FR 40510). The modifications to the two-step attribution methodology also would apply to the methodology used for attributing beneficiaries for the computation of claims based quality measures under §414.1230, except for participants in the Shared Savings Program as described later.

The attribution methodology for the five total per capita cost measures and claims based quality measures in the VM, as finalized in the CY 2013 PFS final rule with comment period (77 FR 66318 through 66320), includes two steps. Before applying the two steps, however, we first identify all beneficiaries who have had at least one primary care service rendered by a

physician in the group. Primary care services include evaluation and management visits in office, other outpatient, skilled nursing facility, and home settings. After this "pre-step", we assign, under Step 1, beneficiaries to the group practice who had a plurality of primary care services (as measured by allowed charges) rendered by primary care physicians in the group, which include Family Practice, Internal Medicine, General Practice, and Geriatric Medicine. If a beneficiary is non-assigned under Step 1, we proceed to Step 2, which is to assign beneficiaries to the group practice whose affiliated non-primary care physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) together provided the plurality of primary care services (as measured by allowed charges), as long as at least one primary care service was provided by a non-primary care physician in the group.

To address NQF concerns regarding the attribution methodology of the total per capita cost measure, we proposed two modifications to the two-step attribution methodology as applied to the five total per capita cost measures, as well as the claims based quality measures in the VM. NQF Committee members discussed how primary care services often are provided by NPs, PAs, or CNSs, but Step 1 of the attribution methodology assigns beneficiaries to the group who had a plurality of primary care services rendered by primary care physicians in the group. After further consideration, we agreed that it is appropriate to include NPs, PAs, and CNSs in Step 1 of the attribution method insofar as they provide primary care services. Consequently, we proposed to move these NPs, PAs, and CNSs from Step 2 of the attribution method to Step 1. This change would affect all five of the total per capita cost measures under §414.1235(a)(1) through (5) and the claims-based quality measures under §414.1230.

Additionally, we proposed to remove the "pre-step" described above for the purposes of the value modifier. The "pre-step" was included in the Shared Savings Program assignment methodology to comply with the statutory requirement (77 FR 67851) that beneficiary

assignment be based upon the utilization of primary care services furnished by a physician. However, no such limitation exists for the VM. Consequently, we proposed to remove the "pre-step" that identifies a pool of assignable beneficiaries that have had at least one primary care service furnished by a physician in the group. Removing the "pre-step" would result in streamlining the attribution process and attributing beneficiaries based on a plurality of primary care services according to Step 1 and Step 2. In addition, we believe that this proposal would help ensure that beneficiaries can be assigned to group practices made up of nonphysician eligible professionals because it would eliminate the criterion that a beneficiary have at least one primary care service furnished by a physician in the group practice. This change (removing the "pre-step") would affect all five of the total per capita cost measures under §414.1235(a)(1) through (5) and the claims-based quality measures under §414.1230.

The two-step attribution rule would remain intact after these two modifications, and the method would continue to be generally consistent with the method of assignment of beneficiaries under the Shared Savings Program, as specified under §414.1240. As discussed previously, the "pre-step" would be removed. We would assign, under Step 1, beneficiaries to the group who had a plurality of primary care services (as measured by allowed charges) rendered by primary care physicians, NPs, PAs, or CNSs in the group. If a beneficiary is non-assigned under Step 1, we still would proceed to Step 2, which would assign beneficiaries to the group practice whose affiliated non-primary care physicians provided the plurality of primary care services (as measured by allowed charges). We proposed these modifications only for groups and solo practitioners who are not participating in the Shared Savings Program. We noted that for groups and solo practitioners who participate in the Shared Savings Program, we would not remove the pre-step or change the attribution methodology for quality measures and cost measures, but would continue to rely on the methodology used by the Shared Savings Program to attribute

beneficiaries to ACOs in the Shared Savings Program. Because we are not applying these assignment changes to Shared Savings Program ACO participants, there is no need to recalculate Shared Savings Program assignment.

One of the reasons we originally proposed this two-step attribution process for the total per capita cost measures and claims based quality measures was that it was aligned with the attribution methodologies used by the Shared Savings Program and also the PQRS GPRO web interface (77 FR 69318 through 69320). We recognize that these programs may seek to establish changes to their methodologies, and noted that for the purposes of the VM, we intended to retain the two-step beneficiary attribution methodology that was described in the CY 2013 PFS final rule with comment period (77 FR 69318 through 69320), subject to the changes proposed above. However, to address the concerns raised by NQF, we believe the proposed modification to the two-step beneficiary attribution method would more appropriately reflect the multiple ways in which primary care services are provided, which are not limited to physician groups. We welcomed comments on our proposed modification to the two-step attribution methodology as applied to the five total per capita cost measures under §414.1235(a)(1) through (a)(5) and to the claims-based quality measures under §414.1230 of the VM.

The following is summary of the comments we received on our proposed modification to the two-step attribution methodology as applied to the five total per capita cost measures under §414.1235(a)(1) through (5) and to the claims-based quality measures under §414.1230 for the VM.

Comment: Many commenters opposed our proposal to modify the two-step attribution methodology. The commenters stated that it would not be appropriate to include NPs, PAs and CNSs in the first step of the attribution methodology because these nonphysician practitioners are not necessarily practicing in a primary care setting. The commenters expressed concern that,

unlike for physicians, there is no specialty distinction on claims billed by NPs, PAs, or CNSs. Therefore, CMS would not be able to distinguish between those practitioners who are practicing in primary care settings and those who are in non-primary care settings. Commenters believe that moving NPs, PAs, and CNSs to the first step could result in beneficiaries being attributed to a specialty practice instead of a primary care practice. A few commenters stated that this would unfairly affect the cost measure calculations for specialist groups with large numbers of nonphysician practitioners. We did not receive any comments specifically opposing the removal of the "pre-step" from the methodology. Several commenters supported our proposal to modify the attribution methodology. The commenters stated that it is important to recognize the role of nonphysician practitioners in providing primary care to beneficiaries and that these changes create a methodology that more accurately reflects team-based approaches to care.

Response: We appreciate the concerns raised by commenters about the potential impact that the lack of specialty designation for NPs, PAs, and CNSs could have on the cost and claims based quality measures. However, we do not believe that this is likely to occur. In an analysis of the impact of including NPs and PAs in step 1 of the attribution methodology using 2011 data for groups of twenty-five or more eligible professionals, we found that over 97 percent of beneficiaries were attributed to the same group that they had been attributed to under the current methodology. Although this analysis does not exactly replicate the changes we proposed, we believe it is a reasonable indication that the changes will not have the significant impact predicted by commenters. We are conducting additional analysis and will monitor the effect of these changes to ensure they are not having a disproportionately negative effect on a subset of provider types. We appreciate the support of and agree with commenters who believe it is important to recognize the role that many NPs, PAs, and CNSs play as primary care providers. The analysis referenced earlier also found that the inclusion of NPs and PAs in step 1 resulted in

an increase of 2.55 percent to the number of beneficiaries attributed to a group and the number of groups to which at least 20 beneficiaries were attributed increased by 3.4 percent. For these reasons, we agree with the NQF recommendation to include these nonphysician practitioners in the attribution methodology. Further, this attribution change will become even more important as we expand the application of the VM to smaller groups and solo practitioners, to increase the number of patients whom they can be assigned, to receive a cost composite that is other than "average" under the VM.

We are finalizing our policy as proposed. Beginning in the CY 2017 payment adjustment period, we will move NPs, PAs, and CNSs from step 2 of the attribution method to step 1. Additionally we are removing the pre-step under which we first identify all beneficiaries who have had at least one primary care service rendered by a physician in the group. These changes apply to all five total per capita cost measures under §414.1235(a)(1) through (5) and the claims-based quality measures under §414.1230.

Second, NQF committee members raised concerns about the exclusion of certain beneficiaries in the methodology used for the total per capita cost measure. Committee members expressed concern that end-of-life costs were not being captured by the measure. We considered this argument and agreed that it is important to include certain beneficiaries with these costs during the performance period. As a result, we proposed to include certain part-year Medicare FFS beneficiaries. This change would affect all five of the total per capita cost measures under §414.1235(a)(1) through (a)(5). The change would provide a more complete assessment of end of life costs associated with the patients a physician group sees during the year (79 FR 40510).

We proposed to continue excluding other part-year beneficiaries (those who spend part of the performance period in a Medicare Advantage (Part C) plan and those enrolled in Part A only or Part B only for part of the performance period and both Part A and Part B for the remainder of

the performance period) (79 FR 40511). Since 2012 we have applied the same attribution rule as that used for the Medicare Shared Savings Program and the PQRS GPRO Web Interface (77 FR 69318-20). In this regard, excluding part-year Medicare Advantage enrollees would remain consistent with the Shared Savings Program and PQRS GPRO web interface reporting policy. If we were to include these part-year Medicare Advantage enrollees, we would need to determine a method to impute their costs for the portion of the performance period in which they were enrolled in FFS Medicare Parts A and B so that we could compare beneficiaries' annual per capita costs appropriately. Similarly, Medicare Part A only or Medicare Part B only enrollees who were enrolled in both Part A and Part B for only part of the performance period would also require a method to impute their costs if they were no longer excluded. Furthermore, these Part A only or Part B only beneficiaries are excluded from the Shared Savings Program and PQRS GPRO methodology.

We proposed including Medicare FFS beneficiaries who are newly enrolled to Medicare during the performance period and enrolled in both Part A and Part B while in Medicare FFS. Additionally, we noted that while the inclusion of new enrollees is inconsistent with GPRO's methodology, it would be consistent with the Shared Savings Program's methodology (79 FR 40511). We welcomed comments on the inclusion of these part-year beneficiaries. We also welcomed comments on whether other part-year Medicare FFS beneficiaries (that is, those who are part-year Medicare Advantage enrollees or part-year Medicare Part A only or Part B only enrollees) should be included in the five total per capita cost measures under §414.1235(a)(1) through (5) in the VM.

Comment: Some commenters opposed our proposal to include certain part-year Medicare FFS beneficiaries in the five total per capita cost measures because they believe the inclusion of these typically higher cost beneficiaries would inappropriately disadvantage groups

that treat a large percentage of beneficiaries at the end of life. We also received comments in support of our proposal to include certain part-year beneficiaries. These commenters stated that it is important to include as many Medicare beneficiaries in the cost measure calculations as feasible and especially important to capture the often significant costs incurred by beneficiaries at the end of life. One commenter suggested that we should develop an end of life specific cost and quality measure rather than including these costs in the per capita cost measures. We did not receive any comments in opposition to the inclusion of newly eligible beneficiaries in the five total per capita cost measures. One commenter indicated that they do not understand why we would exclude any of the part-year beneficiaries, stating that if we can impute costs for some part-year beneficiaries, we should be able to do so for all part-year beneficiaries.

Response: We appreciate the support of commenters who supported our proposal to include some part-year beneficiaries in the five total per capita cost measures. Part-year beneficiaries include those who receive end-of-life care, which has been correlated with high-cost episodes of care.[24] However, analysis submitted to the Institute of Medicine produced an inconclusive causal relationship between the end of a beneficiary's life and the cost of that care.[25] Indeed, research refutes the assumption that Medicare beneficiaries near the end of life have substantially similar health statuses.[26] Rather, prior diagnoses, a characteristic that we currently adjust for in the VM, accounts for a substantial percentage of the geographic variation in the end-of-life costs. In other words, we believe that the risk adjustment system under the VM program explains approximately the same extent of costs in the general Medicare population as it

[24] Congressional Budget Office, "High-Cost Medicare Beneficiaries." Final Paper (May 2005), *available at* http://www.cbo.gov/sites/default/files/05-03-medispending.pdf
[25] Acumen, "Geographic Variation in Spending, Utilization and Quality: Medicare and Medicaid Beneficiaries" (May 2013), *available at* http://www.iom.edu/Reports/2013/~/media/Files/Report%20Files/2013/Geographic-Variation/Sub-Contractor/Acumen-Medicare-Medicaid.pdf.
[26] Reschovsky JD, et al. "Geographic Variation in Fee-for-Service Medicare Beneficiaries' Medical Costs Is Largely Explained by Disease Burden." Med. Care Res. & Rev. 2013; XX,1-22.

does for the cohort of Medicare beneficiaries near the end of life.[27] In response to concerns raised by commenters, we conducted additional analyses to ensure the inclusion of part-year beneficiaries does not inappropriately negatively impact certain groups or solo practitioners. This analysis, which we plan to post to the Value Modifier website in the near future, showed moderate reliability for the five per capita cost measures continued to be high with the inclusion of certain part-year beneficiaries. For example, for the overall per capita cost measure, 83 percent of TINs had reliability equal to or higher than 0.4 when these part-year beneficiaries were included. We agree that it is important to capture as many beneficiaries and costs in these measures as is reasonably possible especially as the number of beneficiaries new to Medicare increases and we continue to agree with the NQF's recommendation to capture end of life costs in our measures. We believe that the inclusion of newly eligible beneficiaries, who are typically much lower cost and a growing portion of the Medicare program, may offset some of the increased costs associated with beneficiaries at the end of life. We appreciate the suggestion to include cost and quality measures that specifically measure care at the end of life and will take this into consideration as we continue to develop the VM program. We also appreciate the comments in support of including other part-year beneficiaries in our measures and we will continue to look into this possibility.

We are finalizing our policies as proposed. Beginning in the CY 2017 payment adjustment period, we will include certain part-year beneficiaries in the five total per capita cost measures under §414.1235(a)(1) through (5). These part-year beneficiaries include Medicare FFS beneficiaries who are at the end of life in the performance period and Medicare FFS beneficiaries who are newly enrolled in Medicare during the performance period and enrolled in

[27] Medicare decedents and Medicare survivors with similar diagnoses and utilization in the previous year had substantially similar cost profiles. Hogan C, et al. "Medicare Beneficiaries' Costs of Care In the Last Year Of Life." Health Affairs. 2001; 20, 188-195.

both Part A and Part B while in Medicare FFS.

In this final rule with comment period, we chose not to address the other concerns about the total per capita cost measures that were raised by NQF. First, we deferred addressing the issue of whether to incorporate socioeconomic status in our measures until after the NQF has finalized its guidance regarding risk adjustment for resource use measures. Second, we did not propose to include Part D data in the total per capita cost measures at this time due to the complexity of the issue and uncertainty of how to fairly and equitably incorporate the costs. Based on data compiled by the Medicare Payment Advisory Commission (MedPAC), we estimated that approximately 60 percent of Medicare FFS beneficiaries were enrolled in stand-alone Part D in 2013.[28] A significant minority of beneficiaries has prescription drug coverage from a source that is outside of Medicare – such as through retiree coverage from a former employer – but for which Medicare does not have access to the data. Including Part D data would incorrectly indicate higher costs for these beneficiaries with Part D coverage relative to otherwise comparable beneficiaries without such coverage and for whom prescription drug costs cannot be measured directly by CMS. Before we are able to propose inclusion of Part D data, we would need to determine an approach to address this issue. We welcomed comments on suggested methods for including Part D data in the total per capita cost measures.

Comment: Many commenters expressed concern that we are not currently including Part D expenditures in our cost measures. These commenters stated that the exclusion of Part D costs could push providers to prescribe Part D drugs even when the Part B drug is more appropriate for the patient. Additionally, commenter stated that they believe the exclusion of Part D unfairly

28 Please see http://www.medpac.gov/documents/Mar14_EntireReport.pdf for underlying data. We estimated that there were 37.3 million Medicare FFS beneficiaries by subtracting the number of beneficiaries enrolled in Medicare Advantage (14.5 million) from the estimated total number of Medicare beneficiaries using data in table 13-1 (P. 328). We estimated that there were 22.4 million beneficiaries with a stand-alone prescription drug plan, which represented 64 percent of the 35 million beneficiaries with Medicare Part D coverage (p. 355).

harms providers that see sicker patients because they believe that these patients are more likely to require Part B medications. Several commenters suggested that CMS either include Part D costs or exclude Part B drug costs. Others suggested excluding only those Part B costs for drugs that have a Part D equivalent or capping the Part B costs for certain high cost drugs. We did not receive any comments specifically recommending an approach for how Part D costs could be included in our cost measurement.

Response: We appreciate the comments and understand the concerns raised in regard to exclusion of Part D costs. We remain committed to capturing a full picture of the total cost of care and to assessing cost in a fair and consistent manner. We are actively investigating options for operationally including Part D costs in our cost measures and would propose any viable options under future notice and comment rulemaking.

Comment: We received many comments emphasizing the importance of including socioeconomic status in our measures. Commenters believe that this is critical to accurately comparing performance between providers that serve different populations. One commenter stated that socioeconomic status should be used in risk adjusting outcomes measures but should not be used in process measures.

Response: As noted above, we will continue to consider whether it would be appropriate to apply a socioeconomic status adjustment to the measures included in the VM. In August 2014, NQF released a report on this topic with recommendations for the development of socioeconomic risk adjustment methodologies[29]. Consistent with that report, we believe it is important to proceed cautiously on this question. We will take the recommendations in this

[29] National Quality Forum, "Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors." Final Report (2014), *available at* http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx

report into account as we consider potential future refinements to our risk adjustment methodologies. Any changes would be made through rulemaking.

We also received the following comment, which we believe is outside of the scope of our proposals:

Comment: One commenter stated that CMS should revise our attribution methodology to look at "allowed services," rather than "allowed charges." The commenter believes that by looking at "allowed charges" we may be inaccurately attributing beneficiaries to the provider that bills using higher level E&M codes, rather than the provider that sees the patient most often.

Response: We believe that a focus on allowed charges is appropriate for attribution in Medicare payment measures, because the intent is to assess which eligible professional should be held accountable for the payments made. Further, the use of allowed charges in the scenario presented by the commenter would further incentivize providers to correctly code E&M services rendered.

k. Discussion Regarding Treatment of Hospital-Based Physicians

We considered including or allowing groups that include hospital-based physicians or solo practitioners who are hospital-based to elect the inclusion of Hospital Value-Based Purchasing (VBP) Program performance in their VM calculation in future years of the program. We stated that would include hospital performance for the hospital or hospitals in which they practice. We would propose such a change through future notice and comment rulemaking, taking into consideration public comment and any relevant empirical evidence available at that time. We considered this potential policy to expand the performance data included for hospital-based physicians and to better align incentives for quality improvement and cost control across CMS programs. Such a policy would also address public comments we received on the CY 2014 PFS proposed rule (78 FR 74775), suggesting that the Hospital VBP Program total performance

score for the hospital in which a specialist practices should be used in the VM. Commenters made this suggestion, noting that there were limited measures that apply to certain specialties and that those specialties may exercise wide influence over the quality of care provided in a hospital. We noted that a hospital's final Hospital VBP Program performance for a given performance period would not be available to a group at the time that they registered for PQRS reporting, so if we were to establish a voluntary policy where groups could elect to include hospital performance, they would make the election to have that performance included in their VM for a payment adjustment period based on the hospital's historic VBP Program performance which would be known to the TIN at the time of election.

We sought public comment on the appropriate methodology to identify hospital-based groups and solo practitioners for the purpose of having Hospital VBP Program data included or allowing them to elect inclusion of Hospital VBP Program performance data in the VM at the TIN level (70 FR 40511-40512). We suggested that we could either allow self-nomination or set a threshold based on physician billing, in order to determine whether a given physician was hospital-based. We sought comment on whether we should set a threshold for a certain proportion of a group's physicians that would have to meet the criteria, in order for hospital-level performance to be included in the group's VM calculation. We also sought comment on whether to use a set of criteria to determine whether non-physician eligible professionals should be allowed to self-nominate or should automatically have hospital-level performance data included in the calculation of their VM. We requested public comment on potential methods for determining which hospital or hospitals' Hospital VBP Program performance data should be included in a physician TIN's VM and how to weight the hospitals, if more than one was included (79 FR 40512). We welcomed public comment on the approaches we considered, as well as alternative approaches for inclusion of all or part of the Hospital VBP Program TPS into

the VM. In the interest of aligning the HVBP and VM programs, we sought public comment on what criteria we should consider in selecting a subset of Hospital VBP Program measures or domains in the VM, if we were to adopt such a policy. Finally, we requested public comment on the most appropriate approach for including Hospital VBP Program performance into a TIN's VM.

Comment: Commenters generally supported including the Hospital VBP Program performance in the VM, suggesting that it be made voluntary for physicians who meet some threshold of services rendered in the hospital setting. Commenters stated that a 90 percent threshold would be too high.

Response: We appreciate the comments and will take these into consideration as we continue to refine the VM program and improve the coordination between the HVBP and VM programs. We would propose any policy changes through future notice and comment rulemaking.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries.

a. CY 2013 Quality and Resource Use Reports Based on CY 2013 Data and Disseminated in CY 2014.

In September 2014, we made available the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups with fewer than 100 eligible professionals will not be subject to the VM in CY 2015. These reports provide clinically

meaningful and actionable information on several aspects of the performance of a group practice or solo practitioner. The reports present not only data assessing a group practice's or solo practitioner's performance on cost measures and information about the services and procedures contributing most to beneficiaries' costs, but also provide data on their performance on quality measures they report under the PQRS as well as the three outcome measures under §414.1230. For groups of 100 or more eligible professionals that are subject to the VM starting in 2015, the QRURs provide information on how the group's quality and cost performance affects their physicians' Medicare payments in 2015. The reports also contain additional supplementary information on the specialty adjusted benchmarks; inclusion of the individual PQRS measures for informational purposes for EPs reporting PQRS measures as individuals; enhanced drill down tables; and a dashboard with key performance measures. The reports are based on the VM policies that were finalized in the CY 2013 PFS final rule (77 FR 69310) for physician payment adjustments under the VM beginning January 1, 2015, and they provide groups with an opportunity to see how the policies adopted will apply to them.

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.

We developed a prototype set of episodes that expands upon the set of episodes that were described in the CY 2014 PFS final rule with comment period (78 FR 74785). In summer 2014, we distributed Supplemental QRURs based on 2012 data to a greater number of groups (groups

with at least 100 EPs[30]EPs) that included a broader set of episodes than the 2011 Supplemental QRURs. In addition to the five clinical conditions in the 2011 Supplemental QRURs, the 2012 Supplemental QRURs included: chronic congestive heart failure (CHF); chronic obstructive pulmonary disease (COPD)/asthma; acute COPD/asthma; permanent pacemaker system replacement/insertion; and bilateral cataract removal with lens implant. For the 2012 Supplemental QRURs, we broke down these episode types into 20 subtypes altogether. In addition to these 20 episode subtypes, we included in the 2012 Supplemental QRURs 6 clinical episode-based measures that we are adapting from those considered for inclusion in the Hospital VBP program (79 FR 28122 through 28124). We described the 20 episode subtypes and six clinical episode-based measures in the proposed rule and sought comment on the three medical and three surgical episode measures that we included in the 2012 Supplemental QRURs.

We did not receive any general comments on the three medical and three surgical episode measures that we included in the 2012 Supplemental QRURs.

Attribution for the six clinical episode-based measures at the group level are the same as the rules used for comparable types of the 20 episode subtypes in the 2012 Supplemental QRURs as discussed above. Attribution rules varied depending on whether a clinical episode-based measure was one of the three surgical (or procedural) episodes or one of the three medical (or acute condition) episodes. Further details on attribution rules can be found in "Detailed Methods of the 2012 Medical Group Practice Supplemental Quality and Resource Use Reports (QRURs)" at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html.

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30 For Supplemental QRUR purposes, groups were also included if they did not to participate in multiple accountable care organizations (ACOs) and did not to participate in more than one of the following initiatives in program year 2012: the Shared Savings Program, the Pioneer Accountable Care Organization (ACO) Model, or the Comprehensive Primary Care Initiative (CPCI).

Specifications for these six clinical episode-based measures, including the MS-DRG and procedure codes used to identify each of the episodes, and details of episode construction methodology, are available in "Detailed Methods of the 2012 Medical Group Practice Supplemental Quality and Resource Use Reports (QRURs)" at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html. We welcomed public comments on these specifications and the construction of the six clinical episode-based measures that we included in the 2012 Supplemental QRURs.

The following is summary of the comments we received on these specifications and the construction of the six clinical episode-based measures that we included in the 2012 Supplemental QRURs.

Comment: One commenter stated that because E&M services are used as the basis for attribution for acute and chronic episodes, they believe it is unlikely that most radiology groups would have a score calculated for these measures. The commenter also noted that certain procedural episode measures, not currently under consideration for inclusion in the VM, may be calculated for radiology groups. Another commenter stated that he believes there are inconsistencies and errors in the attribution methodology used for episode measures.

Response: We understand the concerns of specialists, including radiology groups, about the challenge of identifying measures for which they would have a sufficient number of attributed beneficiaries to have the measures calculated. We will take these into consideration as we continue to refine the measures and consider them for future use in the VM.

CMS' episodes will continue to evolve over the coming years as more experience is gained. More information about the Supplemental QRURs can be found at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html.

We will continue to seek stakeholder input as we develop the episode framework. We considered proposing to add episode-based payment measures to the VM through future rulemaking for all 12 episode subtypes, or some subset of these episode subtypes, of the selected respiratory and selected heart conditions that have appeared in both the 2011 Supplemental QRURs and 2012 Supplemental QRURs. These 12 episode subtypes include: pneumonia (all), pneumonia without an inpatient hospitalization, pneumonia with an inpatient hospitalization, acute myocardial infarction (now called acute coronary syndrome or ACS), ACS without percutaneous coronary interventions (PCI) or coronary artery bypass graft (CABG), ACS with PCI, ACS with CABG, coronary artery disease (now called ischemic heart disease or IHD), IHD without ACS, IHD with ACS, CABG without preceding ACS, and PCI without preceding ACS. Additionally, we are considering proposing to add hospital episode-based payment measures to the VM at a later time, such as the six hospital episodes described above. We welcomed public comments on the specifications included on the website and the construction of the episode-based payment measures that we considered.

The following is summary of the comments we received on the specifications included on the website and the construction of the episode-based payment measures that we considered.

Comment: Several commenters supported our continued efforts to develop episode-based payment measures. Two of these commenters indicated that they believe these measures will support better coordination of care across settings. One commenter suggested that the development of episode measures should follow a similar process to that used for quality measures, including multi-stakeholder expert consensus, evidence-based medicine, and clinical guidelines, as appropriate. We received a few comments stating that the episode measures

should not be included in the VM at this time. Two commenters stated their belief that the episode measures are not currently tied to quality measures and suggested that we address that concern before incorporating the measures into the VM. Another commenter stated that they believe the episode measures are duplicative of the care already captured in the MSPB measure and expressed concern about the reliability of the measures. This commenter suggested that these measures should be removed from the supplemental QRURs until these reliability concerns are addressed. Another commenter suggested that CMS conduct a more thorough analysis of the attribution methodology used in the episode measures and that we narrow the scope of the conditions that are currently included in the episode measures before introducing them into the VM.

Response: We appreciate the input of commenters. We share the commenters' beliefs that coordination across care settings is an important factor in improving quality of care and cost performance. We understand the concerns raised about duplication across cost measures and will take that and the other feedback we received regarding attribution, tying the cost measures to quality measures and the vetting process for measures as we continue to refine the measures and consider them for future use in the VM. Developing a more robust set of cost measures for the VM remains an important goal.

c. Future Plans for the Physician Feedback Reports

In the proposed rule, we stated that we will continue to develop and refine the annual QRURs in an iterative manner and we will seek to further improve the reports by welcoming suggestions from our stakeholders.

As noted previously, on September 30, 2014, we made available the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups with fewer than 100 eligible professionals will not be subject to the VM in CY 2015. These reports contain

performance on the quality and cost measures used to score the composites and additional information to help physicians coordinate care and improve the quality of care furnished. We also intend to provide semi-annual reports with updated cost and utilization data. We will again solicit feedback from physicians and continue to work with our partners to improve them. We note that physicians will have some time to determine the impact of our revised policies and revise their practices accordingly before the new policies impact them. We look forward to continue working with the physician community to improve the QRURs.

We received the following general comments on the Physician Feedback Program:

Comment: Many commenters stated their support for the Physician Feedback Program and applauded CMS's efforts to improve the QRURs. Many commenters stated that we should provide QRURs to providers earlier in the year to give them more time to analyze the results and make adjustments prior to the following calendar year. Several commenters also suggested that QRURs should be distributed to all providers, including nonphysician eligible professionals. Some commenters suggested that CMS increase our education and outreach efforts to ensure that providers know how to access and use the QRURs.

Response: We appreciate commenters support for the Physician Feedback Program and we will take these comments into consideration as we continue to develop and improve the Physician Feedback Program. While it is not feasible to provide the annual QRURs earlier in the year while still allowing sufficient time for claims run out and reporting period, we are exploring how to provide semi-annual reports that will allow groups and solo practitioners to better track their performance on cost and utilization during the year.

O. Establishment of the Federally Qualified Health Center Prospective Payment System (FQHC PPS)

In the May 2, 2014 **Federal Register**, we published the final rule with comment period (79 FR 25436) entitled "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 1998 Enforcement Actions for Proficiency Testing Referral; Final Rule" (herein, "FQHC PPS final rule"). This final rule with comment period implemented methodology and payment rates for federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act, and contained other provisions. In this final rule with comment period, we invited comments on how payment for chronic care management (CCM) services could promote integrated and coordinated care in FQHCs and rural health clinics (RHCs). We also invited comments on the modification of our proposed policy to allow exceptions to the FQHC PPS per diem payment for subsequent illness or injury and mental health services furnished on the same day as a medical visit; the establishment of FQHC G-codes to report and bill FQHC visits to Medicare under the PPS; and the modification of our proposed approach to waiving coinsurance for preventive services when furnished with other services under the FQHC PPS.

1. Promoting integrated and coordinated care in FQHCs and RHCs through payment for Chronic Care Management (CCM) services.

In the FQHC PPS final rule with comment period, we invited comments from FQHCs and RHCs on how payment for CCM services could help to promote integrated and coordinated care in FQHCs and RHCs. We cited the CCM information in the CY 2014 PFS final rule with comment period (78 FR 74230) for physicians billing under the PFS in 2015. We encouraged

FQHCs and RHCs to review this information and submit comments to us on how the CCM services payment could be adapted for FQHCs and RHCs to promote integrated and coordinated care.

We received a few comments regarding how the CCM services payment could be adapted for FQHCs in CY 2015 to provide integrated and coordinated care in FQHCs. Commenters supported adopting the CCM provisions in FQHCs but had concerns about the unique challenges FQHCs would face implementing these provisions. The following is a summary of these comments.

Comment: Commenters stated that the seven initiatives outlined in the CY 2014 PFS final rule with comment period are viable in FQHCs, but noted that FQHCs would face unique challenges when implementing this provision. Commenters stated that the provisions requiring electronic exchange of information might prove difficult at this time since many FQHCs are using electronic health records but are still working on developing the interoperability with other providers. Commenters suggested the requirement to provide patients with secure messages via the internet would be difficult since many FQHC patients are at or below 200 percent of the federal poverty level (FPL) and do not have access to internet or email. For example, a commenter stated that 94 percent of all FQHC patients in one state were below 200 percent of the FPL in 2012. Commenters supported adopting these provisions for FQHCs and suggested that we implement requirements that do not place an undue burden on the health centers or the patient population. One commenter urged that the additional G-codes for CCM services be sufficient to cover the associated costs of documenting care coordination and another commenter expressed concern for appropriate payment and requested that we develop a risk-adjusted per patient per month CCM fee.

Response: We appreciate the comments and will take them into consideration.

2. Exceptions to the per diem FQHC PPS payment for subsequent illness or injury and mental health services furnished on the same day as a medical visit.

FQHCs receive enhanced payment to reflect all costs associated with a visit in a single day by a Medicare beneficiary, regardless of the length or complexity of the visit or the number or type of practitioners seen. Under the all-inclusive rate (AIR) system, an exception to the one encounter payment per day policy was made for situations when a patient comes into the FQHC for a medically necessary visit, and after leaving the FQHC, has a medical issue that was not present at the visit earlier that day, such as an injury or unexpected onset of illness. In these situations, the FQHC has been paid separately for two visits on the same day for the same beneficiary. Under the AIR system, we also allowed separate payment for mental health services furnished on the same day as a medical visit, separate payment for diabetes self-management training/medical nutrition therapy (DSMT/MNT), and separate payment for the initial preventive physical exam (IPPE).

In the FQHC PPS proposed rule, published in the September 23, 2013 **Federal Register** (78 FR 58386), we stated that 2011 Medicare FQHC claims data was reviewed to determine the frequency of FQHCs billing for more than one visit per day for a beneficiary, and we analyzed the potential financial impact on both FQHCs and on access to care if billing for more than 1 visit per day for these situations was no longer permitted. We also considered several alternative options, such as an adjustment of the per visit rate when multiple visits occur in the same day, or the establishment of a separate per visit rate for subsequent visit due to illness or injury, mental health services, DSMT/MNT, or IPPE.

An analysis of data from Medicare FQHC claims with dates of service between January 1, 2011 and June 30, 2012, indicated that multiple visits billed on the same day constituted less than 0.5 percent of all visits, even though the ability to do so has been in place

since 1992 for subsequent illness/injury, since 1996 for mental health services, and since 2007 for DSMT/MNT. We concluded that even allowing for any underreporting in the data, eliminating the ability to bill for multiple visits on the same day would not significantly impact either the FQHC payment or a beneficiary's access to care. Therefore, we proposed to revise §405.2463(b) to remove the exception to the single encounter payment per day for FQHCs paid under the proposed PPS, and we stated that this policy is consistent with an all-inclusive methodology and reasonable cost principles and would simplify billing and payment procedures.

In the FQHC PPS proposed rule, we solicited comments to address whether there are factors that we have not considered, particularly in regards to the provision of mental health services, and whether this change would impact access to these services or the integration of services in underserved communities.

Although we did not receive any information that showed a direct link between multiple billing on the same day and increasing access to care, we modified our proposal in the final rule and stated that we will allow separate billing for subsequent illness or injury occurring on the same day as another medical visit. We also modified our proposal in the FQHC PPS final rule to allow separate billing for mental health services furnished on the same day as a medical visit, as the comments we received led us to conclude that this had the potential to increase access to care, even if the current claims data did not show that this option was being utilized. We invited comments on these modifications.

We received many comments on the modifications to our proposed policy, which would allow an exception to the per diem PPS payment for subsequent injury or illness and for mental health services furnished on the same day as a medical visit. All of the commenters were supportive of this modification; however, most of the commenters requested additional exceptions to the per diem PPS payment. The following is a summary of these comments.

Comment: Most commenters strongly supported our decision to allow separate payment for subsequent injury or illness and mental health services furnished on the same day as a medical visit. Commenters stated that allowing separate payment for mental health services when primary care services are furnished would facilitate integrated and comprehensive health care to Medicare beneficiaries, and agreed with our assertion that separate payment for mental health services has the potential to increase access to mental health services in underserved areas. The commenters also stated that our modification demonstrated our commitment to the value of furnishing mental health services in FQHCs.

Many of the commenters who supported our modification allowing subsequent injury or illness and mental health services to be billed separately when furnished on the same day as another billable visit also requested additional exceptions to the PPS per diem payment system. They noted that under the AIR payment system, DSMT/MNT services and the IPPE can be billed separately when furnished on the same day as another billable visit, and requested that these services also have an exception under the PPS. Commenters particularly emphasized the need for separate payment for DSMT/MNT services and suggested that not being able to bill separately for a DSMT/MNT visit that occurs on the same day as another billable medical visit would deter efficient provision of these services.

Response: We appreciate the support for allowing an exception to the per diem payment when a subsequent injury or illness occurs and for mental health services furnished on the same day as a medical visit.

Commenters are correct that IPPE and DSMT/MNT can be billed as a separate visit under the AIR payment system when furnished on the same day as another medical visit, and that we did not include IPPE or DSMT/MNT in the exceptions under the PPS. As explained in the FQHC PPS proposed rule, an analysis of claims data from FQHCs indicated that the

estimated cost per encounter was approximately 33 percent higher when a FQHC furnished care to a patient that was new to the FQHC or to a beneficiary receiving an IPPE or an annual wellness visit (AWV). If we allowed FQHCs to bill separately for an IPPE that occurred on the same day as another medical visit, we would be overpaying the FQHC for the cost of the IPPE. To accurately pay FQHCs for the costs of furnishing an IPPE, we added an adjustment factor of 1.333 to the PPS rate when an IPPE is furnished at a FQHC. We also extended the adjustment factor to both initial and subsequent AWVs, in order to appropriately compensate FQHCs for the costs of furnishing these services.

In the FQHC PPS proposed rule and final rules, we discussed that we did not include an exception to the per-diem payment for DSMT/MNT because an analysis of the claims and cost reporting data did not justify either a separate per-diem payment or an adjustment to the PPS rate. We also stated our belief that a DSMT/MNT visit is part of the broad category of primary care services that are included in the services of a FQHC and are part of the PPS per diem payment. We noted that visits with multiple practitioners that occur on the same day, including visits for different conditions or visits with a specialist physician, are not separately payable in a FQHC, and we do not believe that DSMT/MNT visits should be considered differently than other primary care services.

Although the comments we received did not persuade us to allow DSMT/MNT to be billed separately in a FQHC when it occurs on the same day as another billable medical visit, or to add an adjustment to the PPS rate for DSMT/MNT when it is furnished on the same day as another billable visit, we believe it is a valuable service, particularly in FQHCs that serve areas with high rates of people with diabetes and related illnesses, and we encourage FQHCs to furnish this service as necessary.

We are retaining §405.2463(c)(4)(i) and §405.2463(c)(4)(ii) as finalized in 79 FR 25478,

which states that for FQHCs billing under the PPS, Medicare pays for more than 1 visit per day when the patient (i) suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or (ii) has a medical visit and a mental health visit on the same day.

3. Establishment of FQHC G-codes to report and bill FQHC visits to Medicare under the PPS.

In the FQHC PPS proposed rule (78 FR 58386), we cited section 1833(a)(1)(Z) of the Act and proposed that Medicare payment under the FQHC PPS would be 80 percent of the lesser of the provider's actual charge or the PPS rate. Commenters were concerned that comparing actual charges with a bundled PPS rate would distort the true cost of services furnished and would result in FQHCs either being forced to increase their charges, or receive payment far below actual cost of furnishing services. In response to these comments, we established a new set of HCPCS G-codes to report an established Medicare patient visit, a new or initial patient visit, and an IPPE or AWV.

We stated that a FQHC would set its charge for the specific payment codes based on its own determination of what would be appropriate for the services normally provided and the population served at that FQHC, and that 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. We emphasized that the use of these payment codes does not dictate to providers how to set their charges, and that detailed HCPCS coding with the associated line item charges would continue to be required along with the payment codes when billing Medicare under the PPS. Medicare would pay FQHCs 80 percent of either the actual charge reported for the specific payment code or the PPS rate on each claim, whichever is lower.

We stated that establishing HCPCS G-codes for FQHCs to report and bill for Medicare

visits would allow comparison between the PPS per diem rate and a FQHC's charge for a per diem visit (as defined by the specific payment codes), and that this would be responsive to commenters' concerns. As we did not propose the establishment of HCPCS G-codes in the proposed rule, nor did we receive public comments specifically requesting such codes, we invited comments on the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS.

We received several comments on the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS. Most commenters favored using G-codes to report and bill FQHC visits under the PPS; however, commenters expressed concerns about the complexity and administrative burden of implementing these codes. The following is a summary of these comments.

Comment: Commenters appreciated that we carefully considered the comments related to the Medicare claims payment process and prefer our development of FQHC payment G-codes to compare the FQHC PPS encounter-based rate with the FQHC's actual charges. Commenters stated that the use of G-codes to implement the "lesser of" provision of the statute is a positive solution that allows for parity between the PPS payment rate and the actual charges being compared. Commenters stated that we resolved what they believe would have resulted in an "apples to oranges" comparison by implementing a system that compares the PPS per diem rate, defined by the specific payment HCPCS G-codes, to a FQHC's actual charge for a per diem visit.

Although many of the commenters were supportive of the establishment of G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS, many of these commenters stated that the process of developing charges for typical bundles of services will be complex for FQHCs. Commenters stated that FQHCs have had limited experience working with

payors who use a "lesser of" or "actual charges" payment methodology. Commenters acknowledged that Medicare regulations require that charges must be neutral among payors; however, given that other payors and paying patients would not be purchasing a precise bundle of services corresponding to the Medicare FQHC visit, commenters stated that the policy to develop G-codes charges is not straightforward. Commenters stated that the charges developed for the FQHC payment G-codes would not be used for any non-Medicare patient. Commenters also stated that it would be challenging for FQHCs to develop charges for a typical bundle of services and adhere to requirements under section 330 of the Public Health Service (PHS) Act, which requires FQHCs to develop charges consistent with locally prevailing rates that cover their reasonable costs of operation. Commenters stated that in developing actual charges, FQHCs would need to perfect their coding capabilities and appropriately capture the bundle of services they provide in the charges. Although some commenters emphasized the complexity of developing G-code charges, a few commenters appreciated that we did not establish precise methods for FQHCs to develop their own G-code charges.

Response: We understand that developing G-codes for FQHC payment under the PPS is unfamiliar to FQHCs. To assist FQHCs in understanding the new payment system, we held two national training sessions which provided detailed examples of various billing scenarios. A transcript of the presentations and slides from the presentation are posted on our website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html. Additional information is available in the "Medicare Benefit Policy Manual, Chapter 13 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services," and the "Medicare Claims Processing Manual, Chapter 9 - Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC)." In the resources, we discuss the need for each FQHC to select a bundle of services that reflects a typical bundle of services that they would provide to a

new or established Medicare patient at their FQHC for medical and mental health services and IPPE and AWV. We also address how FQHCs set their own charges (which must be consistent with the requirements under section 330 of the PHS Act when applicable), and since charges must be the same for all patients, the charges for the services that are included in the bundle would be totaled to determine the G-code payment amount. We expect that once FQHCs set their charges and select the bundle of services that will be included in the FQHC G-codes, they will adapt well to the process. We would also note that other payors could choose to utilize the FQHC payment G-codes if they choose.

Comment: Many commenters suggested that the use of FQHC payment G-codes would create an additional administrative burden for FQHCs' coding and billing staff. Commenters stated that FQHCs will need to spend additional time explaining the charges on the Explanation of Benefits (EOB) to Medicare beneficiaries since there could be additional charges beyond what the beneficiary typically sees associated with a visit. Some commenters stated that using FQHC payment G-codes could artificially inflate FQHCs' total gross charges, although others stated that some of the financial discrepancies in payment would be resolved once the FQHC receives payment. However, many commenters stated there would be an administrative burden to a FQHC in the short-term as it attempts to resolve balances and financial statements.

Response: FQHCs may initially have to spend additional time explaining changes in charges and the patient's EOB, and we encourage them to keep their patients informed of any changes. We also acknowledge that transitioning to a new payment system will require additional time and patience as all aspects of the billing system will need to be adapted.

We noted in the FQHC PPS final rule that although FQHCs set their own charges, FQHCs that receive grant funding under section 330 of the PHS Act are required to maintain charges that are both consistent with locally prevailing rates or charges and are also reflective of

their reasonable costs of operation. Therefore, we do not expect that the FQHCs will use the payment G-codes to artificially inflate their charges.

Comment: Several commenters were concerned that the use of G-codes would limit the definition or scope of a qualifying face-to-face visit. Commenters stated that we were limiting the scope of FQHC services by requiring that only certain HCPCS codes support the use of each FQHC payment G-code. Commenters stated that services described by codes other than evaluation and management (E/M) services also meet the definition of a face-to-face visit with a qualifying provider. The commenters recommended that for each qualifying visit, the FQHC should be able to enter the corresponding FQHC payment G-code to be eligible for payment.

Response: We disagree that the new PPS may limit the scope of FQHC services. All services that qualified as a billable visit under the AIR payment system continue to qualify as a billable visit under the PPS. There has been no change to the scope of services that may be furnished in a FQHC and no change in the type of visits that qualify as a billable visit as a result of the new payment system. Since the previous payment system did not utilize HCPCS coding to determine payment, we anticipate the new payment system will be more transparent, as all services furnished must have the correct HCPCS codes for accurate payment, along with the appropriate G-code for payment. We would also note that in addition to E/M visits, there are many preventive services that can be billed as stand-alone visits in FQHCs under both the AIR and PPS payment systems.

Comment: A few commenters suggested that we develop more G-codes to account for other types of services furnished in a FQHC and G-codes that address varying patient populations. One commenter suggested that we add an additional 10 to 15 HCPCS codes based on the historical claims data for FQHC visits. Another commenter suggested that due to the complex needs of their FQHC patient population, additional FQHC payment G-codes should

reflect multiple services, intensity, and cost of furnishing services to their complex patient population.

Response: We stated in the FQHC PPS proposed and final rules that our goal for the FQHC PPS is to implement a system in accordance with the statute whereby FQHCs are fairly paid for the services they furnish to Medicare patients in the least burdensome manner possible, so that they may continue to furnish primary and preventive health services to the communities they serve. In developing the FQHC G-codes, we considered whether there should be fewer G-codes, or more G-codes, than the five that we ultimately proposed. The G-codes are designed to reflect a typical bundle of services that a FQHC furnishes to their Medicare patients, and we determined that having more G-codes would be burdensome without providing any advantage in payment accuracy. However, we will monitor the PPS system and will consider adding additional G-codes if necessary.

Comment: A number of commenters requested clarification that the bundle of services taken into account in the G-code charge reflects the total bundle of services for a FQHC visit, rather than just the services furnished on that day. Some commenters also sought clarification on billing the professional component of a preventive service on a day subsequent to the day of the visit. These commenters are concerned whether under the new billing requirements for the FQHC PPS all services are meaningfully included in the encounter payment rate even when a component of the service is furnished on a different date than the actual visit.

Response: The FQHC G-codes reflect the services that the FQHC typically furnishes to a Medicare patient that is either a new or established, medical or mental health patient or a patient receiving an IPPE or AWV. This may be the same bundle of services that are furnished to the patient on a particular day, but is not required to be the same services, as the patient may need more, fewer, or a different set of services on that particular day.

FQHCs may bill for services furnished incident to a visit on the same claim, even if they occur on a different day, as long as the services are furnished in a medically appropriate time frame. For example, if a patient has their blood drawn at the FQHC on a Monday, and sees the FQHC practitioner the following Wednesday, the FQHC would include the venipuncture on the same claim as the visit with the practitioner.

The FQHC G-codes are defined in program instructions in accordance with statutory and regulatory requirements and will be implemented as described.

4. Waiving coinsurance for preventive services when furnished with other services under the FQHC PPS.

In the FQHC PPS proposed rule (78 FR 58386), we proposed that for FQHC claims that include a mix of preventive and non-preventive services, FQHCs would use payments under the PFS to determine the proportional amount of coinsurance that should be waived for payments based on the PPS encounter rate. Since Medicare payment under the FQHC PPS is required to be 80 percent of the lesser of the FQHC's charges or the PPS rate, we proposed that we would continue to use FQHC-reported charges to determine the amount of coinsurance that should be waived for payments based on the FQHC's charge, and that total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the lesser of the FQHC's charge or the PPS rate.

We acknowledged that our proposed approach for waiving coinsurance for preventive services when furnished with other services was complex and may be difficult for FQHCs to implement, and we invited public comment on how this proposal would impact a FQHC's administrative procedures and billing practices. Commenters responded that the proposed system to calculate coinsurance was too complex and burdensome and requested that a simplified system be established.

In the final rule referenced above, we agreed with the commenters, and decided to retain the current method used under the AIR system for calculating coinsurance, with certain modifications. Under the new FQHC PPS, the dollar value of the FQHC's reported line-item charge for the preventive service will be subtracted from the full payment amount, whether payment is based on the FQHC's charge or the PPS rate. Medicare will pay the FQHC 100 percent of the dollar value of the FQHC's reported line-item charge for the preventive service, up to the total payment amount. Medicare also will pay a FQHC 80 percent of the remainder of the full payment amount, and beneficiary coinsurance would be assessed at 20 percent of the remainder of the full payment amount. If the reported line-item charge for the preventive service equals or exceeds the full payment amount, Medicare will pay 100 percent of the full payment amount and the beneficiary will not be responsible for any coinsurance.

We believe that this revised methodology is responsive to commenters request for a simpler method of calculating coinsurance and will be more transparent to beneficiaries. We invited comments on this approach to waiving coinsurance for preventive services based on the dollar value of the FQHC's reported line-item charge for preventive services.

We received many comments on how our finalized policy for calculation of coinsurance for preventive services would affect a FQHC's administrative procedures and billing practices. Most commenters appreciated that we are striving for policies that ease administrative burden; however, many of the commenters thought that our revised approach is still too complex and burdensome to implement. The following is a summary of these comments.

Comment: Most commenters supported that we are striving for a waiver of coinsurance calculation that achieves greater simplicity and promotes fair payment under Medicare. A few commenters stated that our revised approach is a common sense and workable approach to applying this important provision. One commenter stated that this approach would allow for

FQHCs to assess coinsurance at the time services are furnished, potentially increase rates of collection, and reduce administrative burden. Commenters who supported the revised approach requested that we closely monitor how the waiver of coinsurance is calculated and determine if further modifications are needed in the future. Most commenters preferred the revised approach, but some expressed concern that it is still too complex and burdensome. Commenters stated that our methodology for the calculation of coinsurance waiver when the services include a mix of preventive and non-preventive services is too complex for the FQHC staff to accurately determine the coinsurance at the time services are furnished. Commenters suggested that FQHCs would be concerned with overcharging the patient and waive all coinsurance when a mixture of preventive and non-preventive services is furnished. Commenters acknowledged that FQHCs could bill the patient after the MAC issues a remittance advice, but the commenters stated that this would increase bad debt. One commenter stated that the revised approach creates an incentive for FQHCs to offer fewer services at each visit and request patients to return on different days for additional services that could have been furnished on the same day.

Response: We appreciate that FQHCs want to accurately determine coinsurance amounts when there is a mix of preventive and non-preventive services furnished on the same day so that beneficiaries are neither overcharged nor undercharged. Since FQHCs set their own charges and develop their own G-codes, they should be able to accurately determine the coinsurance amount. We believe that the proposed method strikes the right balance between accuracy and simplicity, and we will make adjustment as necessary if problems arise. We also note that, under certain circumstances, FQHCs may waive coinsurance amounts for Medicare and Medicaid beneficiaries (see for example, section 1128B(b)(3)(D) of the Act and § 1001.952(k)(2) of the regulations). Also, most FQHCs are subject to the statutory and regulatory requirements of the Health Center Program (section 330 of the PHS Act; 42 CFR Part 51c; and 42 CFR 56.201

through 56.604), which, among other requirements, mandates that they may collect no more than a ‘‘nominal fee’’ from individuals whose annual income is at or below 100 percent of the Federal Poverty Level.”

We are not clear why one commenter suggested that the method for calculating coinsurance could create an incentive for FQHCs to offer fewer services at each visit and request patients to return on different days for additional services that could have been furnished on the same day. However, as we stated in the FQHC PPS final rule, we expect FQHCs to act in the best interests of their patients, which includes scheduling visits in a manner that maximizes the health and safety of their patients.

Comment: Some commenters stated that the complexity of our revised approach does not carry out Congressional intent to provide for complete waiver of coinsurance when covered preventive services are furnished. They stated that when Congress provided for a complete waiver of coinsurance for specific preventive services under section 4104 of the Affordable Care Act, it was intended to improve access to these services, and that requiring Medicare beneficiaries be liable for coinsurance when a mixture of preventive and non-preventive services are furnished does not remove barriers to these services. Commenters also stated that we lack “any specific statutory authorization to waive coinsurance for services provided under the FQHC PPS,” and therefore, CMS is not barred from implementing a complete waiver for coinsurance when a mixture of services are furnished. These commenters stated that a complete waiver of coinsurance for visits involving a preventive service is consistent with the regulation under §410.152(l), which states that Medicare Part B pays “100 percent of the Medicare payment amount established under the applicable payment methodology for the service setting for providers and suppliers of the following preventive services.” Commenters stated that a FQHC is a provider of such preventive services and that the FQHC PPS is an applicable payment

methodology. Commenters surmised that it is more consistent with the regulation to completely waive coinsurance for visits involving a mixture of preventive and non-preventive services rather than implement a partial coinsurance methodology.

Response: We disagree with the commenters' interpretation that the statutory and regulatory language cited provides us with the authority to waive coinsurance for all services when there is a mix of preventive and non-preventive services furnished during a FQHC encounter. The revised methodology for calculating coinsurance when there is a mix of preventive and non-preventive services on the claim was revised in response to commenters' concerns that the methodology that was first proposed was overly complex and burdensome. We believe that the revised methodology is responsive to those concerns, and provides as much simplicity as possible while enabling FQHCs to comply with statutory requirements for the collection of coinsurance.

We are retaining §405.2410(b)(2)(i), §405.2410(b)(2)(ii), and §405.2462(d) of the Medicare regulations as finalized in 79 FR 25475 and will use the current approach to waiving coinsurance for preventive services, whether total payment is based on the FQHC's charge or the PPS rate, by subtracting the dollar value of the FQHC's reported line-item charge for the preventive services from the full payment amount.

5. Other Comments

We received many comments requesting that we provide further information through subregulatory guidance to the stakeholder community regarding same-day visits, development of G-code charges, the calculation of coinsurance when a mixture of preventive and non-preventive services are furnished, what is considered the technical and the professional component of preventive services, billing procedures and processing of claims for same-day visits. Several commenters requested specific examples on calculating coinsurance when the claim contains a

mixture of preventive and non-preventive services.

Response: The "Medicare Benefit Policy Manual, Chapter 13 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services," and the "Medicare Claims Processing Manual, Chapter 9 - Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC), " are regularly updated and will address these topics. Additional information on the FQHC PPS is available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/index.html.

We received some comments that were not related to our specific proposals for the FQHC PPS. Although we appreciate the commenters' feedback on billing for vaccines under Medicare part D, billing for costs relating to language assistance and other enabling services, adjustments to the California GAF, FQHC PPS rate risk adjusters, and the FQHC PPS implementation date, payment for furnishing services to dually eligible Medicare and Medicaid beneficiaries, these topics are beyond the scope of our specific proposals that we specified were subject to public comment in the FQHC PPS.

6. Additional Technical Revisions

a. SNF Consolidated Billing

In this final rule with comment period, we are making a conforming technical revision in §411.15(p)(2) and §489.20(s). In the May 2, 2014, interim final rule (79 FR 25462), we updated §405.2411(b)(2) so that it reflects section 1888(e)(2)(A)(iv) of the Act (as amended by section 410 of the MMA), which excludes certain RHC and FQHC practitioner services from consolidated billing and allows such services to be separately billable under Part B when furnished to a resident of a SNF during a covered Part A stay. This statutory provision was effective with services furnished on or after January 1, 2005 and was previously implemented through program instruction (CMS Pub 100–04, Medicare Claims Processing Manual, Chapter 6,

Section 20.1.1).

However, in making this revision, we inadvertently neglected to make a conforming change in §411.15(p)(2), which enumerates the individual services that are excluded from the SNF consolidated billing provision, as well as in §489.20(s), which specifies compliance with consolidated billing as a requirement of the SNF's Medicare provider agreement. Accordingly, we are now rectifying that omission.

Regarding the technical corrections to parts 411 and 489 of the regulations discussed above, we note that we would ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before revisions in the regulations text would take effect; however, we can waive this procedure if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in connection with these particular revisions, as they merely provide technical corrections to the regulations, without making any substantive changes. Therefore, for good cause, we waive notice and comment procedures for the revisions that we are making to the regulations text in parts 411 and 489.

b. Transitional Care Management

In the May 2, 2014 final rule (79 FR 25436), we added transitional care management (TCM) to §405.2463(a)(1)(ii). To clarify that TCM does not necessarily require a face-to-face visit, we revised this section of the regulation for RHCs, but neglected to add the appropriate reference for FQHCs. Therefore, we are revising §405.2463(a)(2)(i), so that a FQHC visit includes a qualified TCM service.

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 that are reimbursed 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, on January 3, 2013, Congress enacted the American Taxpayer Relief Act of 2012 (ATRA), (Pub. L.112-240), which will delay payment of these drugs under ESRD PPS until January 1, 2016. In the meantime, such drugs furnished in or by an ESRD facility are not reimbursed 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 (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 Addendum K of the CY 2014 PFS final rule with comment period.

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2014.

c. Revisions Effective for 2015

The updated, comprehensive Code List effective January 1, 2015, is available on our Web site at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 90 and 91 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2015. Tables 90 and 91 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 90 and 91. 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 defined in §411.351.

TABLE 90: Additions to the Physician Self-Referral List of CPT[1/]HCPCS Codes

CLINICAL LABORATORY SERVICES
0357T Cryopreservation oocyte(s)
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
97607 Neg press wnd tx </=50 sq cm
97608 Neg press wound tx >50 cm
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
76641 Ultrasound breast complete
76642 Ultrasound breast limited
77061 Breast tomosynthesis uni
77062 Breast tomosynthesis bi
77063 Breast tomosynthesis bi
77085 Dxa bone density study
77086 Fracture assessment via dxa
G0279 Tomosynthesis, mammo screen
RADIATION THERAPY SERVICES AND SUPPLIES
A9606 Radium Ra223 dichloride ther
C2644 Brachytx cesium-131 chloride
77306 Telethx isodose plan simple
77307 Telethx isodose plan cplx
77316 Brachytx isodose plan simple
77317 Brachytx isodose intermed
77318 Brachytx isodose complex

77385 Ntsty modul rad tx dlvr smpl
77386 Ntsty modul rad tx dlvr cplx
G6001 Echo guidance radiotherapy
G6002 Stereoscopic x-ray guidance
G6003 Radiation treatment delivery
G6004 Radiation treatment delivery
G6005 Radiation treatment delivery
G6006 Radiation treatment delivery
G6007 Radiation treatment delivery
G6008 Radiation treatment delivery
G6009 Radiation treatment delivery
G6010 Radiation treatment delivery
G6011 Radiation treatment delivery
G6012 Radiation treatment delivery
G6013 Radiation treatment delivery
G6014 Radiation treatment delivery
G6015 Radiation tx delivery imrt
G6016 Delivery comp imrt
G6017 Intrafraction track motion
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90630 Flu vacc iiv4 no preserv id
G0464 Colorec CA scr, sto bas DNA

[1]CPT codes and descriptions only are copyright 2014 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 91: Deletions from the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0059T Cryopreservation oocyte
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
74291 Contrast x-rays gallbladder
76645 Us exam breast(s)
77082 Dxa bone density vert fx
RADIATION THERAPY SERVICES AND SUPPLIES
0073T Delivery comp imrt
0197T Intrafraction track motion
77305 Teletx isodose plan simple
77310 Teletx isodose plan intermed
77315 Teletx isodose plan complex
77326 Brachytx isodose calc simp
77327 Brachytx isodose calc interm
77328 Brachytx isodose plan compl
77403 Radiation treatment delivery
77404 Radiation treatment delivery
77406 Radiation treatment delivery
77408 Radiation treatment delivery
77409 Radiation treatment delivery
77411 Radiation treatment delivery
77413 Radiation treatment delivery
77414 Radiation treatment delivery
77416 Radiation treatment delivery
77418 Radiation tx delivery imrt
77421 Stereoscopic x-ray guidance
G0417 Sat biopsy prostate 21-40
G0418 Sat biopsy prostate 41-60
G0419 Sat biopsy prostate: >60
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1] CPT codes and descriptions only are copyright 2014 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

Q. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program

1. Statutory Basis

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA) amended titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of CEHRT. Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals, and CAHs, respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments, but do not provide for downward payment adjustments.

Sections 1848(a)(7)(B), 1886(b)(3)(B)(ix)(II), and 1814(l)(4)(C) of the Act provide that the Secretary may, on a case-by-case basis, exempt an EP, eligible hospital, or CAH that is not a meaningful EHR user for an EHR reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP, eligible hospital, or CAH that practices or is located in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an exception be granted for more than 5 years.

2. Provisions of the Interim Final Rule With Comment Period

a. Extreme and Uncontrollable Circumstances Hardship Exception

In the September 4, 2014 **Federal Register** (79 FR 52910-52933) CMS and ONC published a final rule titled "Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule" ("2014 CEHRT Flexibility rule"). The final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to issues related to 2014 Edition CEHRT availability delays to continue to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014, respectively. These CEHRT options applied only to those providers that could not fully implement 2014 Edition CEHRT to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. The final rule also made changes to the attestation process to support these flexible options for CEHRT, although it did not alter the attestation or hardship exception application deadlines for 2014. Therefore, for example, eligible hospitals that never successfully attested to meaningful use prior to FY 2014 were still required to attest by July 1, 2014, and eligible professionals who never successfully attested to meaningful use prior to CY 2014 were required to attest by October 1, 2014, for an EHR reporting period in FY 2014 or CY 2014, respectively, to avoid the Medicare payment adjustments in FY 2015 or CY 2015, respectively. To request a hardship exception from the Medicare payment adjustments in FY or CY 2015, applications were due from eligible professionals by July 1, 2014, eligible hospitals by April 1, 2014, and CAHs by November 30, 2015. In addition, throughout the course of the year, we continued to urge providers to purchase 2014 Edition CEHRT and not wait until the last minute to attest for the

EHR reporting period in 2014.

However, following publication of the 2014 CEHRT Flexibility rule, we became aware that providers were confused over their ability to use flexible options provided under the 2014 CEHRT Flexibility rule, especially given the unchanged attestation deadlines. We received numerous letters from various health care associations, multiple questions from stakeholders on provider calls, and numerous e-mails from providers and EHR vendors, all expressing confusion and seeking clarification about whether they could use the flexible options provided under the 2014 CEHRT Flexibility rule. Specifically, providers were unsure how they could use the flexible options given that the attestation deadlines for both eligible professionals (October 1, 2014) and eligible hospitals (July 1, 2014) would have occurred on or before the effective date of the 2014 CEHRT Flexibility rule (October 1, 2014). Providers were extremely concerned that their inability to use the flexible options specified in the 2014 CEHRT Flexibility rule would subject them to a payment adjustment in 2015 under Medicare for failing to demonstrate meaningful use of CEHRT. This fear was compounded by the fact that the hardship exception application deadlines for both eligible professionals (July 1, 2014) and eligible hospitals (April 1, 2014) had already passed.

In particular, we became aware that eligible professionals who never successfully attested to meaningful use for the EHR Incentive Program were especially affected by this issue because they would not be able to use the flexibility options outlined in the 2014 CEHRT Flexibility rule before the October 1, 2014 deadline to avoid the payment adjustment in CY 2015, because these options could not be made available in the CMS Registration and Attestation System prior to the October 1, 2014 effective date of the 2014 CEHRT Flexibility rule. We also became aware that eligible professionals also faced uncertainty if they joined practices that were already using 2011 Edition CEHRT and experienced delays in full implementation of 2014 Edition CEHRT.

Therefore, we understood that eligible professionals were concerned that the inability to attest by October 1, 2014 using the flexible options under the 2014 CEHRT Flexibility rule would potentially subject them to the payment adjustment in CY 2015 authorized under the Medicare EHR Incentive Program if they could not receive a hardship exception.

Accordingly, to ensure that all providers can use the flexible options recently finalized under the 2014 CEHRT Flexibility rule for an EHR reporting period in 2014, and ensure that providers are not potentially subjected to the 2015 payment adjustment under the Medicare EHR Incentive Program, we are recognizing a hardship exception under the established category of "extreme and uncontrollable circumstances" under 42 CFR § 495.102(d)(4)(iii) for eligible professionals and § 412.64(d)(4)(ii)(B) for eligible hospitals, pursuant to the Secretary's discretionary hardship exception authority. Under this IFC, we will consider that an extreme and uncontrollable circumstance hardship exists for an eligible professional or eligible hospital if two criteria are met. First, the provider must not have been able to fully implement the 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. Second, the provider must not have been able to attest by their attestation deadline in 2014. For example, for eligible professionals, the eligible professional must not have been able to attest by October 1, 2014 using the flexibility options under the 2014 CEHRT Flexibility rule. For eligible hospitals, the eligible hospital must not have been able to attest by July 1, 2014 using the flexibility options under the 2014 CEHRT Flexibility rule. We will recognize an extreme and uncontrollable circumstance hardship exception under this IFC only for those providers meeting both these criteria and only for the 2015 payment adjustment.

For CAHs, although we would recognize a hardship exception for CAHs under these circumstances, this exception would have little impact on CAHs because the hardship exception application deadline for CAHs for the 2015 payment adjustment does not occur until November

30, 2015. Accordingly, CAHs will have ample time to attest using the flexibility options under the 2014 CEHRT Flexibility rule and will not be impacted in the same manner as eligible hospitals or eligible professionals, whose attestation and hardship exception application deadlines have since passed. However, as explained below, to maximize flexibility in the hardship exception application submission process for all providers under the hardship exception categories, so that we avoid similar situations in the future, like the ones prompting this IFC, we are amending §413.70(a)(6) to allow CMS the flexibility to specify an alternate hardship exception application submission deadline for certain hardship categories other than November 30th.

b. Extension of Hardship Exception Application Deadline to November 30, 2014 for Eligible Professionals and Eligible Hospitals and Amendments to §§495.102, 412.64, and 413.70.

Section 495.102(d)(4) provides the categories of hardship exceptions for EPs, including insufficient internet access, newly practicing EPs, extreme circumstances outside of an EP's control, lack of control over the availability of CEHRT for EPs practicing in multiple locations, lack of face-to-face patient interactions and lack of need for follow-up care, and certain primary specialties. With the exception of the newly practicing EP hardship exception category, the EP is required to file a hardship exception application to CMS for the remaining hardship categories no later than July 1st of the year before the payment adjustment year.

Similar to eligible professionals, §412.64(d)(4) provides the categories of hardship exceptions for eligible hospitals, which include insufficient internet access, new eligible hospitals, and extreme and uncontrollable circumstances outside of an eligible hospital's control. Under the hardship exception categories for insufficient internet access and extreme and uncontrollable circumstances, the eligible hospital is required to file a hardship exception application to CMS no later than April 1st of the year before the payment adjustment year.

Similar to eligible hospitals, §413.70(a)(6) provides the categories of hardship exceptions that CAHs could apply for, which include insufficient internet access, new CAHs, and extreme and uncontrollable circumstances outside of a CAH's control. Under all hardship exception categories, the CAH is required to file a hardship exception application to CMS no later than November 30th after the close of the applicable EHR reporting period for a payment adjustment year to be considered for a hardship exception.

For purposes of the 2015 payment adjustment under the Medicare EHR Incentive Program, the hardship exception application deadlines for both eligible hospitals and eligible professionals have ended. However, we need to accommodate the extreme and uncontrollable circumstance hardship exception recognized under this IFC. Therefore, for purposes of the 2015 payment adjustment under the Medicare EHR Incentive Program, we are extending the hardship exception application submission deadline for both eligible hospitals and eligible professionals to November 30, 2014. We believe that extending the hardship exception application deadline to November 30, 2014 will allow ample time for those eligible hospitals and eligible professionals that could not fully implement 2014 Edition CEHRT due to 2014 Edition CEHRT availability delays and that could not attest by their applicable attestation deadline using the flexibility options provided in the 2014 CEHRT flexibility rule to file an application for the hardship exception recognized under this IFC.

The extension of the hardship exception application submission deadline to November 30, 2014, applies only to those providers who meet the criteria described under this IFC. We will not extend, reopen, or reconsider the hardship exception application deadline for the 2015 payment adjustment for any other reason. Further, as explained above, because CAHs have still not reached their November 30, 2015 hardship exception application deadline, they are not affected in the same manner as eligible hospitals and eligible professionals, and are still eligible

to file a hardship exception application until November 30th under any of the categories specified under §413.70(a)(6).

Next, to extend the hardship exception application deadline to November 30, 2014, for eligible hospitals and eligible professionals, we must amend under this IFC the July 1st hardship exception application deadline for extreme and uncontrollable circumstances under §495.102(d)(4)(iii) for eligible professionals and the April 1st deadline under §412.64(d)(4)(ii)(B) for eligible hospitals. For eligible professionals, the new amendment to §495.102(d)(4)(iii) will include, following the July 1st hardship exception application submission deadline specified in the regulation, language that would enable CMS to specify a later deadline. For eligible hospitals, the new amendment to §412.64(d)(4)(ii)(B) will include, following the April 1st hardship exception application submission deadline specified in the regulation, language that would enable CMS to specify a later deadline. We are making these regulatory amendments under this IFC to allow eligible hospitals and eligible professionals to take advantage of the extreme and uncontrollable circumstances hardship exception outlined under this IFC. Without such changes, eligible hospitals and eligible professionals would be unable to apply for this hardship exception because the application deadlines have already passed.

Finally, we note that, as with the circumstances described in this IFC that caused us to extend the deadline to November 30, 2014, there may be situations in the future that would warrant extending the July 1st deadline for eligible professionals, the April 1st deadline for eligible hospitals, and the November 30th deadline for CAHs. Accordingly, to ensure that we do not face similar timing constraints in the future and to reduce administrative burden on providers who wish to request a hardship exception, we are amending the regulation text for the other hardship exception categories to enable CMS to specify a later deadline for submission of hardship exception applications.

Specifically, for eligible professionals, in addition to the amendments we cited above for §495.102(d)(4)(iii) relating to the extreme and uncontrollable circumstances hardship exception category, we are also amending §495.102(d)(4)(i) (insufficient internet access) and (d)(4)(iv) (multiple locations/lack of face-to-face encounters and need for follow-up/certain primary specialties) to add similar language.

For eligible hospitals, in addition to the amendments we cited above for §412.64(d)(4)(ii)(B) relating to the extreme and uncontrollable circumstances hardship exception category, we are also amending §412.64(d)(4)(ii)(A) (lack of internet access) to add similar language.

For CAHs, we are amending §413.70(a)(6)(ii) to add language similar to the language added to the regulation text for eligible professionals and eligible hospitals, as discussed above. We believe that the flexibility to specify a later hardship exception application submission deadline as set forth above will prevent situations such as the one addressed under this IFC where, for example, an unforeseen circumstance occurred, which could justify a hardship exception, but the hardship exception application submission deadline has passed. However, we emphasize that we do not intend to exercise this flexibility to extend the hardship exception application submission deadline frequently. Rather, to maintain the consistency needed for our operations, providers should expect to adhere to the dates specified in the regulation text and not rely on the possibility of changes to the hardship application submission period occurring on a frequent basis.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Unless noted otherwise, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the Bureau's June 2012 Employer Costs for Employee Compensation report.

In the CY 2015 PFS proposed rule (79 FR 40317), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Information Collection Requirements (ICRs)

1. ICRs Regarding the Removal of Employment Requirements for Services Furnished Incident to Rural Health Clinics and Federally Qualified Health Center Visits

This provision removes the requirement that nonphysician RHC or FQHC practitioners be W-2 employees. This action does not require the modification of existing contracts or the creation of new contracts, nor does CMS collect any information on contracting. Consequently, the provision is not subject to the requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

2. ICRs Regarding Access to Identifiable Data for the Center for Medicare and Medicaid Models

This provision concerns the evaluation of models tested under, section 1115A of the Act. Section 1115(A)(d)(3) of the Act provides that the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) shall not apply to the testing, evaluation or expansion of models under section 1115A of the Act.

3. ICRs Regarding Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

The proposed Clinical Diagnostic Laboratory LCD Process will not be finalized. Consequently, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) and the LCD process do not apply to this final rule.

4. ICRs Regarding the Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements

The proposed rule solicited comment on substitute billing arrangements and did not set out any new or revised collection of information requirements. Consequently, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) is not applicable.

5. ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904(c)(8), (d)(3), and (g))

With regard to the following provisions, no PRA-related comments were received. The proposed provisions are being adopted without change.

In §403.904(c)(8), applicable manufacturers and applicable group purchasing organizations (GPOs) must report the marketed name and therapeutic area or product category of covered drugs, devices, biologicals and medical supplies. The amendment has non-measurable effect on current burden estimates since the manufacturers and GPOs are already required to report the marketed name for drugs and biologicals and report the marketed name, therapeutic area, or product category for devices and medical supplies. While the requirement has no burden implications, the provision will be submitted to OMB for approval under control number 0938-1173 (CMS-10419).

In §403.904(d)(3), applicable manufacturers and applicable GPOs must report the form of payment or other transfers of value as: cash or cash equivalent, in-kind items or services, stock, stock option, or any other ownership investment. The burden associated with this provision is the time and effort it will take each applicable manufacturer and applicable GPO to revise their reporting system to report the form of payment.

The removal of §403.904(g) requires that applicable manufacturers and applicable GPOs of covered drugs, devices, biologicals, and medical supplies report annually to CMS all payments or other transfers of value provided as compensation for speaking at a continuing education program. The ongoing burden associated with this provision is the time and effort it will take each applicable manufacturer and applicable GPO to report payments or other transfers of value to CMS which were provided to physicians at a continuing education program. We estimate that it will take 1.0 hour to report payments or other transfers of value to CMS which were provided to physician at a continuing education program.

We estimate that it will take 1.0 hour to report payments or other transfers of value to CMS which were provided to physician covered recipients as compensation for speaking at a continuing education program and 0.5 hours to revise an applicable manufacturer or applicable GPO's reporting system to report the form of payment.

In deriving these figures, we used the following hourly labor rates and estimated the time to complete each task: $26.39/hr and 1.0 hours for support staff to report payments or other transfers of value to CMS which were provided to physician covered recipients as compensation for speaking at a continuing education program and $4+7.55/hr and 0.5 hours for support to revise their reporting system to report the form of payment.

The preceding requirements and burden estimates will be added to the existing PRA-related requirements and burden estimates that have been approved by OMB under control number 0938-1173 (CMS-10419).

6. ICRs Regarding Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

With regard to the following provisions, no PRA-related comments were received. The proposed provisions are being adopted without change.

The annual burden estimate is calculated separately for the 2017 PQRS payment adjustment (the reporting periods of which occur in 2015): (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR, (3) EHR-based reporting mechanisms, and (4) group practices using the group practice reporting option (GPRO). Please note that we are grouping group practices using the qualified registry and EHR-based reporting mechanisms with the burden estimate for individual eligible professionals using the qualified registry and EHR-based reporting mechanisms because we believe the criteria for satisfactory reporting for group practices using these 2 reporting

mechanisms under the GPRO are similar to the satisfactory reporting criteria for eligible professionals using these reporting mechanisms.

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Reporting in General

According to the 2012 Reporting Experience, "more than 1.2 million eligible professionals were eligible to participate in the 2012 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model."[31] In this burden estimate, we assume that 1.2 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2012, will be eligible to participate in the PQRS. Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. Therefore, we believe that although 1.2 million eligible professionals will be subject to the 2017 PQRS payment adjustment, not all eligible participants will report quality measures data for purposes of the 2017 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 2017 PQRS payment adjustment.

In 2012, 435,871 eligible professionals (36 percent of 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 Shared Savings Program or Pioneer ACO model) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.[32] We expect to see a significant increase in participation in reporting for the PQRS in 2015 than 2012 as eligible professionals were not subject to a PQRS payment adjustment in 2012. Last year, we estimated that we would see a 50 percent participation rate in 2015. We still believe

[31] 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.
[32] Id. at XV.

that a 14 percent increase in participation from 2012 is reasonable in 2015. Therefore, we estimate that 50 percent of eligible professionals (or approximately 600,000 eligible professionals) will report quality measures data for purposes of the 2017 PQRS payment adjustment.

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals 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 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 assume that a billing clerk will handle the administrative duties associated with participating in the PQRS. According to information published by the Bureau of Labor Statistics, available at http://www.bls.gov/oes/current/oes433021.htm, the mean hourly wage for a billing clerk is approximately $32.00/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of $32.00/hour. In addition, for purposes of this burden estimate, we assume that a computer analyst will engage in the duties associated with the reporting of quality measures. According to information published by the Bureau of Labor Statistics, available at http://www.bls.gov/oes/current/oes151121.htm, the mean hourly wage for a computer analyst is approximately $82.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of $82.00/hour.

Please note that, in assessing PQRS-specific burden estimates, to account for benefits and overhead associated with labor in addition to the hourly wage costs described above, we are doubling the wage rates in our estimates. While we accounted for fringe benefits in the NPRM's wage estimates, we did not double the wage rates in those estimates.

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 2017 PQRS payment adjustment, we assume that each eligible professional reports on an average of 9 measures for this burden analysis.

For eligible professionals who are participating in PQRS for the first time, 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 group 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 hours x $32/hour = $160.

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 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 and Group Practices: Claims-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, in 2011, 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.[33] Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.[34]

According to the historical data cited above, while 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. While 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 or the Pioneer ACO Model), 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 assume that approximately 250,000 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. The PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837 P and/or CMS form CMS-1500 (OMB control number 0938-0999). We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837 P or CMS-1500 for CY 2015.

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[33] *Id*. at xvi. *See* Figure 4.
[34] *Id*.

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 $410 per eligible professional ($82 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 will take approximately 2.25 minutes to 108 minutes to perform all of the necessary reporting steps.

Per measure, at an average labor cost of $82/hour per practice, the cost associated with this burden will range from $0.34 to about $16.40 for more complicated cases and/or measures, with the cost for the median practice being $2.40. To report 9 measures, using an average labor cost of $82/hour, we estimated that the cost of reporting for an eligible professional via claims will range from $3.07 (2.25 minutes or 0.0375 hours x $82/hour) to $147.60 (108 minutes or 1.8 hours x $82/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 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).

Based on these assumptions, we estimate that the total annual reporting burden per individual eligible professional associated with claims based reporting will range from 13.5 minutes (0.25 minutes per measure x 9 measures x 6 cases per measure) to 648 minutes (12 minutes per measure x 9 measures x 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure x 9 measures x 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims based reporting will range from $18.36 ($0.34 per measure x 9 measures x 6 cases per measure) to $885.60 ($16.40 per measure x 9 measures x 6 cases per measure), with the cost to the median practice being $129.60 per eligible professional ($2.40 per measure x 9 measures x 6 cases per measure).

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and 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. According to the 2012 Reporting Experience, 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.[35] Therefore, approximately 47,000 eligible professionals participated in the PQRS using the registry-based reporting mechanism in 2012.

[35] *Id*. at xvi. *See* Figure 4.

Please note that we currently have no data on participation in the PQRS via a 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 165,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2015. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

For qualified registry based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be repackaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that

the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

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, in 2011, 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, in 2012, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.[36]

We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will steadily increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging the 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 mechanism. 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 2015.

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[36] *Id*. at xv.

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

For EHR based reporting for the PQRS, the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a 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.

e. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

As we noted in last year's estimate, according to 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.[37] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[38] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[39] Since it seems that roughly 200 group practices participated in the GPRO in 2011 and 2012, based on these numbers, we assume that 200 group practices (accounting for approximately 135,000 eligible professionals) will participate in the PQRS using the GPRO web interface in 2015.

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 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 $32 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

[37] *Id*. at xv.
[38] *Id*. at xvi.
[39] *Id*. at 18.

to a group practice associated with the group practice self-nomination process to be approximately $192 ($32 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 are approved under control number 0938-0941(form CMS-10136) with an expiration date of July 31, 2015, 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 $82 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $6,478.

7. ICRs Regarding the Medicare Shared Savings Program

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.).

8. ICRs Regarding Interim Revisions to the Electronic Health Record (EHR) Incentive Program

This rule does not impose new or alter existing reporting, recordkeeping, or third-party disclosure requirements. Consequently, it need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

9. ICRs Regarding the Extreme and Uncontrollable Circumstances Hardship Exception

With regard to the hardship application, this rule will not impose any new or revised reporting, recordkeeping, or third-party disclosure requirements and therefore, does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The application's information collection requirements and burden have been approved by OMB under OMB control number 0938-1158 (CMS-10336).

B. Summary of Final Burden Estimates

Table 92 summarizes this rule's requirements and burden estimates.

TABLE 92: Annual Recordkeeping and Reporting Requirements and Burden

Regulation Section(s)	OMB & CMS ID #s	Respondents	Responses (total)	Burden (time) per Response	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
403.904(d)(3)	0938-1173 (CMS-10419	1,150 (manufacturers)	1,150	1.0 hr (reporting)	1,150	26.39	30,349
				0.5 hr (system upgrades)	575	47.55	27,341
		420 (GPOs)	420	1.0 hr (reporting)	420	26.39	11,084
				0.5 hr (system upgrades)	210	47.55	9,986
CY 2015 PQRS (start up for first time participants)	0938-1059 (CMS-10276)	164,000	164,000	5 hr	820,000	16.00	13,120,000
CY 2015 PQRS (Claims-Based Reporting Mechanism)	0938-1059 (CMS-10276)	250,000	250,000 (preparation and reporting)	5.2241	1,306,025	82.00	107,090,000
CY 2015 PQRS (Qualified Registry-based and QCDR-based Reporting Mechanisms)	0938-1059 (CMS-10276)	165,000	165,000	5 min	13,750	N/A*	N/A
CY 2015 PQRS (EHR-Based Reporting Mechanism)	0938-1059 (CMS-10276)	50,000	50,000	N/A**	N/A	N/A	N/A
CY 2015 PQRS (Group Practices Using the GPRO Web Interface)	0938-1059 (CMS-10276)	200	200 (self-nomination process)	6 hr	17,000	192.00	1,334,000
			200 (reporting)	79 hr			
TOTAL		630,770	14,130,970	--	2,159,130	--	121,622,760

*There is no set cost. As explained above, the cost will vary depending on the registry used. Additionally, many EPs and group practices using a registry or QCDR will most likely use a registry or QCDR for other purposes.
**As explained above, the burden associated with the submission of data is minimal.

C. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' website at http://www.cms.hhs.gov/PaperworkReductionActof1995; email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov; or call the Reports Clearance Office at 410–786–1326.

When commenting on the stated information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov.

PRA-specific comments must be received by December 1, 2014**[**.

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 and revised codes, it is impracticable for us to provide prior notice and solicit comment on 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 furnished to Medicare beneficiaries by physicians and

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. We assign interim RVUs to any new and revised codes based on a review of the RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific 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 RUC recommendations for only one component (work or PE) but not both. By reviewing these RUC recommendations for the new and revised 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 to other payment policies. If we did not assign RVUs to new and revised 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 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.

This final rule with comment period revises the process we will use to address new, revised in order to minimize the need to establish RVUs on an interim final basis beginning with rulemaking for CY 2017. However, 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 for CY 2015. We are providing a 60-day public comment period.

Section II.E. of this final rule with comment period discusses our review and decisions regarding the RUC recommendations. Similar to the RUC recommendations for new and revised codes previously discussed, due to the timing of the RUC recommendations for the services identified as potentially misvalued codes, it is impracticable for CMS to provide for notice and comment regarding specific revisions prior to publication of this final rule with comment period. 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 RUC, on an interim final basis for CY 2015. The revised RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources involved in 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 distortion in the payment for other services under the PFS. Implementing the changes on an interim basis allows for a more equitable resource-based 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 RUC process allows for an assessment of the valuation of these services by the medical community prior to the RUC's recommendation to CMS. This final rule with comment period revises the process we will use to address misvalued codes in order to minimize the need to establish RVUs on an interim final basis beginning with rulemaking for CY 2017. However, 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 for CY 2015. We are providing a 60-day public comment period.

B. FQHC PPS Rates and Adjustments

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before publishing a final rule that responds to comments and sets forth final regulations that generally take effect at least 30 days later. 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.

In the May 2, 2014, interim final rule (79 FR 25462), we updated §405.2411(b)(2) so that it reflects section 1888(e)(2)(A)(iv) of the Act (as amended by section 410 of the MMA), which excludes certain RHC and FQHC practitioner services from consolidated billing and allows such services to be separately billable under Part B when furnished to a resident of a SNF during a covered Part A stay.

However, in making this revision, we inadvertently neglected to make a conforming change in §411.15(p)(2), which enumerates the individual services that are excluded from the SNF consolidated billing provision, as well as in §489.20(s), which specifies compliance with consolidated billing as a requirement of the SNF's Medicare provider agreement. Accordingly, we are now rectifying that omission in this final rule with comment period, by making a conforming technical revision in §411.15(p)(2) and §489.20(s).

These particular revisions merely provide technical corrections to the regulations, without making any substantive changes. Therefore, for good cause, we waive notice and comment procedures for the revisions to the regulations text in parts 411 and 489.

C. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program

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.

With regard to the interim revisions to the Electronic Health Record (EHR) Incentive Program, we find good cause to waive the notice-and-comment procedure as contrary to the public interest. We believe that providing notice and a comment period would prevent us from providing relief from the circumstances outlined in section III.Q. A delay would interfere with the ability of eligible professionals and eligible hospitals to request a hardship exception for the extreme and uncontrollable circumstances specified under this IFC given that the hardship applications deadlines have since passed for both eligible professionals and eligible hospitals. Any delay to this IFC would potentially subject providers to the 2015 payment adjustment under the Medicare EHR Incentive Program and potentially decrease participation in the EHR Incentive Programs, thereby creating a negative impact to the forward movement of the EHR Incentive Programs. For these reasons, we find good cause to waive the notice of proposed rulemaking for these revisions to the EHR Incentive Program and to establish these revisions on an interim final basis. We are providing a 60-day public comment period.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. The delayed effective date may also be waived in the case of a substantive rule which grants or recognizes an exemption or relieves a restriction. For the reasons set forth below, we believe it

would be contrary to the public interest to delay the effective date of the interim final revisions to the EHR Incentive Program described in section III.Q of this final rule with comment period We also believe these interim final revisions relieve a restriction .

The IFC recognizes a hardship exception based on extreme and uncontrollable circumstances, which could potentially provide relief from the application of the 2015 payment adjustment under the Medicare EHR Incentive Program to certain providers. This IFC would also relieve a restriction by amending the existing deadlines in the regulation text for providers to apply for hardship exceptions from the payment adjustments. Unless these amendments to the deadlines are made effective immediately, eligible hospitals and eligible professionals would not have enough time to take advantage of the November 30th extended hardship exception application submission period specified in this IFC, given that their hardship exception application submission deadlines have since passed. We find good cause to waive the delayed effective date of the interim final revisions to the EHR Incentive Program and find that they relieve an existing restriction by changing the deadlines by which providers must apply for hardship exceptions. These provisions will be effective on [OFR—Insert date of filing for public inspection at OFR].

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Pathway for SGR Reform Act of 2013 and the PAMA. This final rule with comment period also is necessary to make changes to Part B payment policy for clinical diagnostic lab tests and other Part B related policies. This rule also implements aspects of the data collection required under section 1115A(b)(4) of the Act.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this 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 have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's 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 are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, 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 2014, that threshold is approximately $141 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 have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this 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 are implementing a variety of changes to our regulations, payments, or payment policies to ensure

that our payment systems reflect changes in medical practice and the relative value of services, and 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. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice 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 2014 with payment rates for CY 2015 using CY 2013 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each 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 physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the April 2015 conversion factor

changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or "target" expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the "SGR" methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. Although the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2015 on our website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/index.html?redirect=/SustainableGRatesConFact/.

Tables 93 shows the payment impact on PFS services. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Table 93 (CY 2015 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty).

The following is an explanation of the information represented in Table 93:

- Column A (Specialty): The Medicare specialty code as reflected in our physician/supplier enrollment files.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 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 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2015 impact on total allowed charges of the changes in the PE RVUs, including the impact of changes due to new, revised, and misvalued codes, the film-to-digital migration of imaging inputs, and other miscellaneous and minor provisions.
- Column E (Impact of Malpractice (MP) Changes): This column shows the estimated CY 2015 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 (Cumulative Impact): This column shows the estimated CY 2015 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 93: CY 2015 PFS Final Rule with Comment Period Estimated Impact Table: Impacts of Work, Practice Expense, and Malpractice RVUs

(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	$88,045	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$216	0%	0%	0%	0%
ANESTHESIOLOGY	$1,993	0%	0%	0%	0%
AUDIOLOGIST	$60	0%	0%	0%	0%
CARDIAC SURGERY	$355	0%	0%	-1%	-1%
CARDIOLOGY	$6,470	0%	0%	0%	0%
CHIROPRACTOR	$812	0%	0%	-1%	-1%
CLINICAL PSYCHOLOGIST	$704	0%	-1%	0%	-1%
CLINICAL SOCIAL WORKER	$522	0%	-1%	0%	-1%
COLON AND RECTAL SURGERY	$159	0%	0%	0%	0%
CRITICAL CARE	$287	0%	0%	0%	0%
DERMATOLOGY	$3,177	0%	-1%	0%	-2%
DIAGNOSTIC TESTING FACILITY	$715	0%	-2%	0%	-2%
EMERGENCY MEDICINE	$3,046	0%	0%	1%	1%
ENDOCRINOLOGY	$457	0%	0%	0%	0%
FAMILY PRACTICE	$6,107	1%	1%	0%	1%
GASTROENTEROLOGY	$1,884	0%	0%	0%	0%
GENERAL PRACTICE	$506	0%	0%	0%	0%
GENERAL SURGERY	$2,245	0%	0%	0%	0%
GERIATRICS	$227	1%	1%	0%	1%
HAND SURGERY	$160	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	$1,811	0%	1%	0%	1%
INDEPENDENT LABORATORY	$714	-1%	0%	0%	-1%
INFECTIOUS DISEASE	$652	0%	0%	0%	1%
INTERNAL MEDICINE	$11,123	1%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$678	0%	1%	0%	0%
INTERVENTIONAL RADIOLOGY	$273	0%	1%	0%	0%
MULTISPECIALTY CLINIC/OTHER PHY	$84	0%	0%	0%	0%
NEPHROLOGY	$2,181	0%	0%	0%	0%
NEUROLOGY	$1,513	0%	0%	0%	0%
NEUROSURGERY	$740	0%	0%	1%	1%
NUCLEAR MEDICINE	$49	0%	0%	0%	0%
NURSE ANES / ANES ASST	$1,186	0%	0%	0%	0%
NURSE PRACTITIONER	$2,224	0%	0%	0%	1%
OBSTETRICS/GYNECOLOGY	$696	0%	0%	0%	-1%
OPHTHALMOLOGY	$5,685	0%	0%	-2%	-2%

(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
OPTOMETRY	$1,163	0%	0%	-1%	-1%
ORAL/MAXILLOFACIAL SURGERY	$45	0%	0%	0%	0%
ORTHOPEDIC SURGERY	$3,672	0%	0%	0%	-1%
OTHER	$28	0%	0%	-1%	-1%
OTOLARNGOLOGY	$1,174	0%	0%	0%	0%
PATHOLOGY	$1,077	-1%	1%	0%	0%
PEDIATRICS	$59	0%	0%	0%	0%
PHYSICAL MEDICINE	$1,008	0%	0%	0%	0%
PHYSICAL/OCCUPATIONAL THERAPY	$2,836	0%	0%	1%	1%
PHYSICIAN ASSISTANT	$1,565	0%	0%	0%	0%
PLASTIC SURGERY	$374	0%	0%	-1%	0%
PODIATRY	$2,001	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$112	0%	-2%	0%	-2%
PSYCHIATRY	$1,352	0%	0%	0%	0%
PULMONARY DISEASE	$1,795	0%	0%	0%	0%
RADIATION ONCOLOGY	$1,794	0%	0%	0%	0%
RADIATION THERAPY CENTERS	$57	0%	0%	0%	1%
RADIOLOGY	$4,523	0%	-1%	0%	-1%
RHEUMATOLOGY	$541	0%	0%	0%	-1%
THORACIC SURGERY	$343	0%	0%	-1%	-1%
UROLOGY	$1,838	0%	0%	0%	0%
VASCULAR SURGERY	$978	0%	0%	0%	0%

Note: Table 93 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the April 2015 conversion factor change required under current law.

2. CY 2015 PFS Impact Discussion

a. Work RVU Impacts

The changes in work RVU impacts are almost entirely attributable to the payment for CCM services beginning in CY 2015. We finalized this separately billable CCM service in the CY 2014 final rule with comment period, effective beginning in CY 2015 (78 FR 74414 through 74427). We are finalizing a payment rate for CCM services for CY 2015 (see section II.G. of this

final rule with comment period.) Payment for this service is expected to result in modest payment increases for family practice, internal medicine, and geriatrics.

b. PE RVU Impacts

Payment for CCM services also has a positive impact on the PE RVUs attributable to family practice, internal medicine, and geriatrics. The most widespread specialty impacts in PE RVUs are generally related implementing the RUC recommendation regarding the film-to-digital migration of imaging inputs, which primarily affects portable x-ray suppliers, diagnostic testing facilities, and interventional radiology. Other impacts result from adjustments of PE RVUs for services as discussed in section II.A. of this final rule with comment period.

c. MP RVU Impacts

The changes in MP RVUs are primarily attributable to the changes made as part of the statutorily required review of MP RVUs every five years as described in section II.C of this final rule with comment period. Of particular note are the impacts on the specialties of ophthalmology (-2 percent) and optometry (-1 percent). In the course of preparation of the proposed MP RVUs, we discovered that we had made an error in calculating the MP RVUs for ophthalmology codes in the last five year review CY that resulted in higher MP RVUs for ophthalmology and optometry for CY 2010 than would have resulted had the MP RVUs been calculated correctly. The MP RVUs have been at a level higher than they would have been had they been calculated correctly since CY 2010.

d. Combined Impact

Column F of Table 93 displays the estimated CY 2015 combined impact on total allowed charges by specialty of all the RVU changes. These impacts are estimated prior to the application of the negative CF update effective April 1, 2015, applicable under the current

statute.

Table 94 (Impact of Final rule with comment period on CY 2015 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the changes discussed previously. We have included payment rates for the period of January 1, 2015 through March 31, 2015, as well as those for April 1, 2015 through December 31, 2015. We selected these procedures for the 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 of this final rule with comment period.

TABLE 94: Impact of Final Rule with Comment Period on CY 2014 Payment for Selected Procedures

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2014[2]	CY 2015 Jan 1– March 31[3]	% Change	CY 2015 April 1 – December 31[4]	% Change	CY 2014[2]	CY 2015 Jan 1– March 31[3]	% Change	CY 2015 April 1 – December 31[4]	% Change
11721		Debride nail 6 or more	$25.43	$25.42	0%	$20.04	-21%	$45.14	$45.47	1%	$35.84	-21%
17000		Destruct premalg lesion	$53.38	$53.70	1%	$42.34	-21%	$75.23	$66.95	-11%	$52.78	-30%
27130		Total hip arthroplasty	$1,395.30	$1,399.11	0%	$1,102.99	-21%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	$1,262.04	$1,270.23	1%	$1,001.38	-21%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	$1,394.58	$1,398.76	0%	$1,102.08	-21%	NA	NA	NA	NA	NA
33533		Cabg arterial single	$1,956.28	$1,936.13	-1%	$1,526.35	-22%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	$1,200.42	$1,192.90	-1%	$940.42	-22%	NA	NA	NA	NA	NA
43239		Egd biopsy single/multiple	$152.25	$152.16	0%	$119.95	-21%	$405.51	$409.92	1%	$323.16	-20%
66821		After cataract laser	$324.55	$315.05	-3%	$248.37	-23%	$342.47	$333.67	-3%	$263.05	-23%
66984		Cataract surg w/iol 1 stage	$673.11	$647.65	-4%	$510.57	-24%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	$523.37	$506.95	-3%	$399.58	-24%	$540.92	$524.49	-3%	$413.48	-24%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	$24.00	$22.55	-6%	$17.78	-26%
71010	26	Chest x-ray 1 view frontal	$9.31	$9.31	0%	$7.34	-21%	$9.31	$9.31	0%	$7.34	-21%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	$116.07	$116.00	0%	$91.45	-21%
77056	26	Mammogram both breasts	$44.42	$44.39	0%	$35.00	-21%	$44.42	$44.39	0%	$35.00	-21%
77057		Mammogram screening	NA	NA	NA	NA	NA	$82.75	$82.70	0%	$65.20	-21%
77057	26	Mammogram screening	$35.82	$35.80	0%	$28.22	-21%	$35.82	$35.80	0%	$28.22	-21%
77427		Radiation tx management	$186.28	$186.17	0%	$146.76	-21%	$186.28	$186.17	0%	$146.76	-21%
88305	26	Tissue exam by	$38.33	$39.02	2%	$30.76	-20%	$38.33	$39.02	2%	$30.76	-20%
90935		Hemodialysis one	$73.44	$73.03	-1%	$57.58	-22%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	$54.81	$52.99	-3%	$41.77	-24%	$87.05	$85.57	-2%	$67.46	-23%
92014		Eye exam&tx estab pt	$82.75	$80.55	-3%	$63.50	-23%	$126.10	$124.23	-1%	$97.94	-22%
93000		Electrocardiogram	NA	NA	NA	NA	NA	$16.84	$17.18	2%	$13.55	-20%
93010		Electrocardiogram report	$8.60	$8.59	0%	$6.77	-21%	$8.60	$8.59	0%	$6.77	-21%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	$75.94	$76.97	1%	$60.68	-20%

			Facility					Non-Facility				
CPT/ HCPCS [1]	MOD	Short Descriptor	CY 2014[2]	CY 2015 Jan 1– March 31[3]	% Change	CY 2015 April 1 – December 31[4]	% Change	CY 2014[2]	CY 2015 Jan 1– March 31[3]	% Change	CY 2015 April 1 – December 31[4]	% Change
93307	26	Tte w/o doppler complete	$45.85	$45.83	0%	$36.13	-21%	$45.85	$45.83	0%	$36.13	-21%
93458	26	L hrt artery/ventricle	$325.63	$321.14	-1%	$253.17	-22%	$325.63	$321.14	-1%	$253.17	-22%
98941		Chiropract manj 3-4	$35.46	$35.09	-1%	$27.66	-22%	$41.55	$41.17	-1%	$32.46	-22%
99203		Office/outpatient visit new	$77.02	$77.69	1%	$61.25	-20%	$108.18	$109.19	1%	$86.08	-20%
99213		Office/outpatient visit est	$51.58	$51.20	-1%	$40.36	-22%	$73.08	$73.03	0%	$57.58	-21%
99214		Office/outpatient visit est	$79.17	$78.76	-1%	$62.09	-22%	$107.83	$107.76	0%	$84.95	-21%
99222		Initial hospital care	$138.63	$138.55	0%	$109.23	-21%	NA	NA	NA	NA	NA
99223		Initial hospital care	$204.19	$204.07	0%	$160.80	-21%	NA	NA	NA	NA	NA
99231		Subsequent hospital care	$39.41	$39.38	0%	$31.05	-21%	NA	NA	NA	NA	NA
99232		Subsequent hospital care	$72.36	$73.03	1%	$57.58	-20%	NA	NA	NA	NA	NA
99233		Subsequent hospital care	$104.24	$105.61	1%	$83.26	-20%	NA	NA	NA	NA	NA
99236		Observ/hosp same date	$219.24	$219.82	0%	$173.29	-21%	NA	NA	NA	NA	NA
99239		Hospital discharge day	$107.47	$108.12	1%	$85.24	-21%	NA	NA	NA	NA	NA
99283		Emergency dept visit	$61.97	$62.29	1%	$49.11	-21%	NA	NA	NA	NA	NA
99284		Emergency dept visit	$118.22	$119.22	1%	$93.99	-20%	NA	NA	NA	NA	NA
99291		Critical care first hour	$224.61	$225.91	1%	$178.09	-21%	$274.76	$277.10	1%	$218.45	-20%
99292		Critical care addl 30 min	$112.48	$113.13	1%	$89.19	-21%	$123.23	$124.23	1%	$97.94	-21%
99348		Home visit est patient	NA	NA	NA	NA	NA	$84.54	$84.13	0%	$66.33	-22%
99350		Home visit est patient	NA	NA	NA	NA	NA	$178.40	$177.93	0%	$140.27	-21%
G0008		Immunization admin	NA	NA	NA	NA	NA	$25.08	$25.42	1%	$20.04	-20%

[1] CPT codes and descriptions are copyright 2014 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] The CY 2014 conversion factor is 35.8228.
[3] Payments based on the CY 2015 conversion factor of 35.8013 effective January 1 – March 31.
[4] Payments based on the CY 2015 conversion factor of 28.2239 effective April 1.

D. Effect of Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E. of this final rule with comment period, we are finalizing the addition of 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 these additions.

E. Geographic Practice Cost Indices (GPCIs)

As discussed in section II.D of this final rule with comment period, we are required to review and revise the GPCIs at least every 3 years and phase in the adjustment over 2 years (if there has not been an adjustment in the past year). For CY 2015, we are not making any revisions related to the data or the methodologies used to calculate the GPCIs except in regard to the Virgin Islands locality discussed in section II.D. However, since the 1.0 work GPCI floor provided in section 1848(e)(1)(E) of the Act is set to expire on March 31, 2015, we have included two set of GPCIs and GAFs for CY 2015—one set for January 1, 2015 through March 31, 2015 and another set for April 1, 2015 through December 31, 2015. The April 1, 2015 through December 31, 2015 GPCIs and GAFs reflect the statutory expiration of the 1.0 work GPCI floor.

F. Other Provisions of the Final Rule with Comment Period Regulation

1. Ambulance Fee Schedule

The 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 §414.610(c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

The geographic designations for approximately 92.02 percent of ZIP codes would be unchanged if we adopt OMB's revised statistical area delineations and the updated RUCA codes. There are more ZIP codes that would change from rural to urban (3,038 or 7.08 percent) than from urban to rural (387 or 0.90 percent). The differences in the data provided in the proposed rule compared to the final rule are due to inclusion of the updated RUCA codes. In general, it is expected that ambulance providers and suppliers in 387 ZIP codes within 41 states may experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. Ambulance providers and suppliers in 3, 038 ZIP codes within 46 states and Puerto Rico may experience payment decreases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. None of the current super rural areas will lose their status upon implementation of the revised OMB delineations and the updated RUCA codes. We estimate that the adoption of the revised OMB delineations and the updated RUCA codes would have a small fiscal impact on the Medicare program.

2. Clinical Laboratory Fee Schedule

There is no impact because we are merely deleting language from the Code of Federal Regulations.

3. Removal of Employment Requirements for Services Furnished "Incident to" RHC and FQHC Visits

The removal of employment requirements for services furnished "incident to" RHC and FQHC visits will provide RHCs and FQHCs with greater flexibility in meeting their staffing needs, which may result in increasing access to care in underserved areas. There is no cost to the federal government, and we cannot estimate a cost savings for RHCs or FQHCs.

4. Access to Identifiable Data for the Center for Medicare and Medicaid Models

Given that, in general, participants in Innovation Center models receive funding support to participate in model tests, we do not anticipate an impact. In those cases where there is a cost associated with the data reporting, such costs will vary by project, and thus cannot be laid out with specificity here. We do, however, expect the costs to be covered by payments associated with the model test.

5. Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests

The Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests will not be finalized. Therefore, there is no impact to CY 2015 physician payments under the PFS.

6. Private Contracting/Opt Out

We corrected cross-references and outdated terminology in the regulations that we inadvertently neglected to revise, and changed the appeals process used for certain appeals relating to opt-out private contracting. We anticipate no or minimal impact as a result of these corrections.

7. Payment Policy for Locum Tenens Physicians

We did not issue any new or revised requirements. There is no impact.

8. Reports of Payments or Other Transfers of Value to Covered Recipients

The changes to the Transparency Reports and Reporting of Physician Ownership or Investment Interests in section III.I of this final rule with comment period would not impact CY 2015 physician payments under the PFS.

9. Physician Compare

There will be no impact for the Physician Compare website because we are not collecting any new information specifically for the Physician Compare website. The information derived for Physician Compare comes from other programs that already collect data, including but not limited to the Physician Quality Reporting System (PQRS) and the Medicare Shared Savings

Program.

10. Physician Quality Reporting System

According to the 2012 Reporting Experience, "more than 1.2 million eligible professionals were eligible to participate in the 2012 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model."[40] In this burden estimate, we assume that 1.2 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2012, will be eligible to participate in the PQRS. Since all eligible professionals are subject to the 2017 PQRS payment adjustment, we estimate that all 1.2 million eligible professionals will participate, (which includes, for the purposes of this discussion, being eligible for the 2017 PQRS payment adjustment) in the PQRS in 2015 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2017 PQRS payment adjustment.

Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. Therefore, we believe that although 1.2 million eligible professionals will be subject to the 2017 PQRS payment adjustment, not all eligible participants will actually report quality measures data for purposes of the 2017 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 2017 PQRS payment adjustment. In 2012, 435,871 eligible professionals (36 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 Shared Savings Program or Pioneer ACO Model) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.[41] We expect to see a

[40] 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.
[41] Id. at XV.

significant increase in participation in reporting for the PQRS in 2015 than 2012 as eligible professionals were not subject to a PQRS payment adjustment in 2012. Last year (78 FR 74793), we estimated that we would see a 50 percent participation rate in 2015. We still believe that a 14 percent increase in participation from 2012 is reasonable in 2015. Therefore, we estimate that 50 percent of eligible professionals (or approximately 600,000 eligible professionals) will report quality measures data for purposes of the 2017 PQRS payment adjustment.

For participation in the PQRS using the claims-based reporting mechanism, according to the 2011 PQRS and eRx Experience Report, in 2011, 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.[42] Preliminary estimates show that 252,567 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2013.[43] 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 percentage of participants using the claims-based reporting mechanism in the PQRS. 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 or Pioneer ACO model), 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 250,000 eligible professionals will participate in the PQRS using the claims-based

[42] *Id*. at xvi. *See* Figure 4.
[43] *Id*.

reporting mechanism.

For participation in the PQRS using a qualified registry or QCDR, in 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. According to the 2012 Reporting Experience, 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.[44] Therefore, approximately 47,000 eligible professionals participated in the PQRS using the registry-based reporting mechanism in 2012. Please note that we currently have no data on participation in the PQRS via a 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: (1) the PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures; or (2) 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 (the remaining number of eligible professionals not participating via the claims, EHR, or GPRO web interface reporting mechanisms) to approximately 165,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2015. 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 participation in the PQRS using the EHR-based reporting mechanism, according to the 2011 PQRS and eRx Experience Report, in 2011, 560 (or less than 1 percent) of the 320,422

[44] *Id*. at xvi. *See* Figure 4.

eligible professionals participating in PQRS used the EHR-based reporting mechanism. 2012 saw a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, in 2012, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.[45] We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will steadily increase 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 2015.

For participation in the PQRS using the GPRO web interface, as we noted in last year's estimate, according to 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.[46] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[47] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[48] Since it seems that roughly 200 group practices participated in the GPRO in 2011 and 2012, based on these numbers, we will assume that 200 group practices

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[45] *Id*. at xv.
[46] *Id*. at xv.
[47] *Id*. at xvi.
[48] *Id*. at 18.

(accounting for approximately 135,000 eligible professionals) will participate in the PQRS using the GPRO web interface in 2015.

Please note that, while we are finalizing the reporting of CAHPS survey measures using a CMS-certified survey vendor, we are not including this reporting mechanism in this impact statement as we believe that eligible professionals wishing to report CAHPS survey measures will do so for purposes other than the PQRS.

(a) Assumptions for Burden Estimates

For the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals 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 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. According to information published by the Bureau of Labor Statistics, available at http://www.bls.gov/oes/2013/may/oes433021.htm, the mean hourly wage for a billing clerk is approximately $16.80/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of $16.00/hour. In addition, for purposes of this burden estimate, we will assume that a computer analyst will engage in the duties associated with the reporting of quality measures. According to information published by the Bureau of Labor Statistics,

available at http://www.bls.gov/oes/2013/may/oes151121.htm, the mean hourly wage for a computer analyst is approximately $41.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of $41.00/hour. Please note that, in assessing the burden estimates below, to account for benefits and overhead associated with labor in addition to the hourly wage costs described above, we are doubling the wage rates in our estimates.

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 2017 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 for the first time, 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. We believe 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 group 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 hours x $32/hour = $160.

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

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. The PQRS will collects QDCs as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500 (OCN: 0938-0999).

We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CY 2015.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures group 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 $410 per eligible professional ($82 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 $82/hour per practice, the cost associated with this burden will range from $0.34 in labor to about $16.40 in labor time for more complicated cases and/or measures, with the cost for the median practice being $2.40. To report 9 measures, using an average labor cost of $82/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $3.07 (2.25 minutes or 0.0375 hours x $82/hour) to $147.60 (108 minutes or 1.8 hours x $82/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).

Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional associated with claims-based reporting will range from 13.5 minutes (0.25 minutes per measure x 9 measures x 6 cases per measure) to 648 minutes (12 minutes per measure x 9 measures x 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure x 9 measures x 6 cases). We estimate the total annual reporting cost per eligible professional or eligible professional in a group practice associated with claims-based reporting will range from $18.36 ($0.34 per measure x 9 measures x 6 cases per measure) to $885.60 ($16.40 per measure x 9 measures x 6 cases per measure), with the cost to the median practice being $129.60 per eligible professional ($2.40 per measure x 9 measures x 6 cases per measure).

(c) Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and QCDR-based Reporting Mechanisms

For qualified registry-based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be re-packaging the data for use in the PQRS. Little, if

any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above and in Part B of this supporting statement, Table 95 provides an estimate of the total annual burden hours and total annual cost burden associated with eligible professionals using the qualified registry-based or QCDR-based reporting mechanism. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to us on quality measures on multiple occasions, an eligible professional would not be required to submit this data to us, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

(d) Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the our 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 us from their EHR or utilize an EHR data submission vendor to submit the data to us on the eligible professional's or group practice's behalf. To submit data to us directly from their EHR, the eligible professional or

eligible professional in a group practice must have access to our 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 our 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 our 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 us, 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.

(e) Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff. 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 $32 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 $192 ($32 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 $82 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $6,478.

Tables 95 and 96 provide our total estimated costs for reporting in the PQRS for the 2017 PQRS payment adjustment, the reporting periods of which occur in CY 2015.

TABLE 95: Summary of Burden Estimates for Eligible Professionals and/or Group Practices using the Claims, Qualified registry, and EHR-based Reporting Mechanisms for the 2017 PQRS Payment Adjustment

	Minimum Burden Estimate	**Maximum Burden Estimate**
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	**1,306,025**	**3,948,920**
Estimated Annual Burden Hours for Qualified registry-based or QCDR-based Reporting	**1,333,695**	**1,333,695**
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	**3,089,720**	**5,732,615**
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	**$107,090,000**	**$323,900,000**
Estimated Cost for Qualified registry-based Reporting	**$109,362,000**	**$109,362,000**
Estimated Cost for EHR-based Reporting	**$32,800,000**	**$32,800,000**
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	**$249,252,000**	**$466,062,000**

TABLE 96: Estimated Costs of Group Practices using the GPRO Web Interface to Participate in the PQRS for the 2017 PQRS Payment Adjustment

	Maximum Burden Estimate
Estimated # of Participating Group Practices	200
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	**17,000**
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	$192
Estimated Cost Per Group Practice to Report Quality Measures	$6,478
Estimated Total Annual Cost Per Group Practice	$6,670
Annual Burden Cost for Group Practices	**$1,334,000**

11. EHR Incentive Program

The changes to the EHR Incentive Program in section III.L of this final rule with comment period would not impact CY 2015 physician payments under the PFS.

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). The proposals for the Medicare Shared Savings Program set forth in the CY 2015 MPFS proposed rule revisited the current quality performance standard, proposed changes to the quality measures, proposed modifications to the timeframe between updates to the quality performance benchmarks, and proposed to establish an additional incentive to reward ACO quality improvement. Since the policies being adopted in this final rule with comment period do not increase the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants and ACO providers/suppliers, there is no impact for these policies.

13. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a 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.

The changes to the VM in section III.N of this final rule with comment period will not impact CY 2015 physician payments under the PFS. We finalized the VM policies that would impact the CY 2015 physician payments under the PFS in the CY 2013 PFS final rule with comment period (77 FR 69306-69326).

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. 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 eligible professionals that also may bill under the TIN. We established CY 2013 as the performance period for the VM that will be applied to payments during CY 2015 (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).

We finalized policies to determine the amount of the VM for CY 2015 by categorizing groups of physicians with 100 or more eligible professionals into two categories. Category 1 includes groups of physicians that either (a) self-nominate for the PQRS as a group and report at

least one measure or (b) elect the PQRS Administrative Claims option as a group. Category 2 includes groups that do not fall within either of the two subcategories (a) or (b) of Category 1. Groups within Category 1 may elect to have their VM for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The VM for groups of physicians in Category 1 that do not elect-quality tiering is 0.0 percent, meaning that these groups will not receive a payment adjustment under the VM for CY 2015. For the groups that are in Category 2, the VM for the CY 2015 payment adjustment period is -1.0 percent.

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. We compare the group's quality of care composite classification with the cost composite classification to determine the VM adjustment for the CY 2015 payment adjustment period according to the amounts in Table 97.

TABLE 97: 2015 Value-Based Payment Modifier Amounts under Quality-Tiering

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	-0.5%	+0.0%	+1.0x*
High Cost	-1.0%	-0.5%	+0.0%

* Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the downward payment adjustments in Table 97 for those groups in Category 1 that have elected quality tiering with the -1.0 percent downward payment adjustments for groups of physicians subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). These calculations will be done after the performance period has ended.

In the proposed rule, we presented estimates on the number of eligible professionals and physician groups, by group size, based on CY 2012 claims data that were used to produce the 2012 QRURs, which were available to groups of 25 or more eligible professionals on September 16, 2013. The findings from the CY 2012 QRURs are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2012-QRUR.html in a document titled "Experience Report for the Performance Year 2012 Quality and Resource Use Reports".

On September 30, 2014, we made QRURs available to all groups of physicians and physicians who are solo practitioners based on their performance in CY 2013. We also completed the analysis of the impact of the VM in CY 2015 on physicians in groups with 100 or more eligible professionals based on their performance in CY 2013 and present a summary of the findings below. Please note that the impact of the policies for the CY 2017 VM finalized in this final rule with comment period will be discussed in the PFS rule for CY 2017.

Based on the methodology codified in §414.1210(c), there are 1,010 groups of 100 or more eligible professionals (as identified by their Taxpayer Identification Numbers (TINs)) whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2015 payment adjustment period. Of these 1,010 groups subject to the CY 2015 VM, 706 groups met the criteria for inclusion in Category 1. As noted above, Category 1 for the CY 2015 VM includes groups of physicians that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group.

Of the 706 groups in Category 1, 133 groups elected in 2013 to have their CY 2015 VM calculated using the quality-tiering methodology; therefore, these groups will receive an upward, neutral, or downward adjustment in CY 2015 based on their performance on the quality and cost measures finalized for the CY 2015 VM in the CY 2013 PFS final rule with comment period (77

FR 69306-69326). We note that there were 21 groups for which we had insufficient data to calculate their quality or cost composite; therefore, these groups will receive a neutral adjustment to their payments in CY 2015. Of the 112 groups for which we were able to calculate both quality and cost composites, we found that 16 groups are in tiers that will result in an upward adjustment of +1.0x; 9 groups are in tiers that will result in a downward adjustment of between -0.5 and -1.0 percent; and 87 groups are in tiers that will result in a neutral adjustment to their payments in CY 2015. Of the groups that are eligible for an upward adjustment, none of the groups are eligible to receive an additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries. Table 98 shows the distribution of the 112 groups that elected quality-tiering into the various quality and cost tiers. Please note that CMS will announce the upward payment adjustment factor (x) in the Fall of 2014 on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html.

TABLE 98: Distribution Using 2013 Data of Quality and Cost Tiers for Groups with 100 or More Eligible Professionals that Elected Quality-Tiering for Which a Quality and Cost Composite Score Could Be Calculated (112 Groups)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0% (0)	+1.0x (2)	+2.0x (0)
Average Cost	-0.5% (5)	+0.0% (87)	+1.0x (14)
High Cost	-1.0% (2)	-0.5% (2)	+0.0% (0)

Of the 706 groups in Category 1, 573 groups elected to not have their CY 2015 VM calculated using the quality-tiering methodology; therefore, their VM will be 0.0 percent, meaning that these groups will not receive a payment adjustment under the VM in CY 2015.

Of the 1,010 groups subject to the CY 2015 VM, 304 groups met the criteria for inclusion in Category 2. As noted above, Category 2 includes groups that do not fall within either of the

two subcategories (a) or (b) of Category 1. There were 289 groups that did not self-nominate for the PQRS as a group, and 15 groups that self-nominated for the PQRS as a group, but did not report at least one measure. Groups in Category 2 will be subject to a -1.0 percent payment adjustment under the VM during the CY 2015 payment adjustment period.

Please note that in CY 2015, only the physicians in groups with 100 or more eligible professionals that are in Category 1 and elected quality-tiering will be subject to upward, downward, or no payment adjustment under the VM according to Table 98. Additionally, physicians in groups with 100 or more eligible professionals that fall in Category 2 will be subject to the -1.0 percent VM in CY 2015.

We note that in the 2013 QRUR Experience Report, which will be released in the next few months, we will provide a detailed analysis of the impact of the 2015 VM policies on groups of 100 or more eligible professionals subject to the VM in CY 2015, including findings based on the data contained in the 2013 QRURs for all groups of physicians and solo practitioners.

14. Interim Revisions to the Electronic Health Record (EHR) Incentive Program

This interim final rule will allow us flexibility in setting the deadline for significant hardship exception applications. We refer readers to the impact analyses included in the final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2" (77 FR 53698 through 54162) and Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology; Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule (79 FR 52911-52933).

G. 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.

H. 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 the changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS; and revisions to payment for Part B drugs 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 94, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $108.18, which means that in CY 2014 a beneficiary would be responsible for 20 percent of this amount, or $21.64. Based on this final rule with comment period, using the January 1 – March 31, 2015 CF of 35.8013, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 94, is $109.19, which means that, in CY 2015, the beneficiary coinsurance for this service would be $21.84. In addition, we are finalizing a change in our definition of colorectal cancer screening test. As a result, beneficiary liability will not be applied to anesthesia billed in conjunction with a

colorectal cancer screening test.

I. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 99 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2014 to CY 2015 based on the FY 2015 President's Budget baseline. Note that subsequent legislation changed the updates for 2015 from those shown in the 2015 President's Budget baseline.

TABLE 99: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2015 Annualized Monetized Transfers	Estimated decrease in expenditures of $14.7 billion for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2015 Annualized Monetized Transfers	Estimated increase in payment of $234 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 100: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

Category	Transfer
CY 2015 Annualized Monetized Transfers of beneficiary cost coinsurance.	$9 million
From Whom to Whom?	Beneficiaries to Federal Government

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial "Regulatory Flexibility Analysis." The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, 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.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:—

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§403.902 [Amended]

2. In §403.902, remove the definition of "Covered device".

3. Section 403.904 is amended by –

A. Revising paragraphs (c)(8), (d)(3), and (d)(4).

B. Adding paragraphs (d)(5) and (d)(6).

C. Revising paragraph (f)(1)(iv).

D. Removing paragraph (g).

E. Redesignating paragraphs (h) and (i) as paragraphs (g) and (h), respectively.

F. Amending newly redesignated paragraph (h)(2)(ii) by removing "paragraph (i)(2)(i) of this section" and adding in its place "paragraph (h)(2)(i) of this section".

G. Amending newly redesignated paragraph (h)(2)(iii) by removing "paragraph (i)(2)(ii) of this section" and adding in its place "paragraph (h)(2)(i) of this section".

The revisions and additions read as follows:

§403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c) * * *

(8) <u>Related covered drug, device, biological or medical supply</u>. Report the marketed name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area

or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals, if the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on clinicaltrials.gov.

(ii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iii) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(iv) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

* * * * *

(d) * * *

(3) Stock.

(4) Stock option.

(5) Any other ownership interest.

(6) Dividend, profit or other return on investment.

* * * * *

(f) * * *

(1) * * *

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section), for drugs and biologicals, the relevant National Drug Code(s), if any, for devices and medical supplies and report a therapeutic area or product category if a marketed name is not available.

* * * * *

§403.906 [Amended]

4. In §403.906, amend paragraph (b)(6) by removing "§403.904(c) through (i)" and by adding in its place "§403.904(c) through (h)."

5. New subpart K is added to part 403 to read as follows:

Subpart K--Access to Identifiable Data for the Center for Medicare and Medicaid Models

Sec.

403.1100 Purpose and scope.

403.1105 Definitions.

403.1110 Evaluation of models.

Subpart K--Access to Identifiable Data for the Center for Medicare and Medicaid Models

§403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§403.1105 Definitions.

For purposes of this subpart--

Applicable titles means Titles XVIII, XIX, or XXI of the Act.

§403.1110 Evaluation of models.

(a) Evaluation. The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) Information. Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including "protected health information" as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

6. 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).

7. Section 405.400 is amended by revising the definition of "Emergency care services" to read as follows:

§405.400 Definitions.

* * * * *

Emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

* * * * *

§405.420 [Amended]

8. In §405.420, amend paragraph (e), by removing the phrase “Medicare+Choice” and adding in its place the phrase “Medicare Advantage”.

§405.425 [Amended]

9. In §405.425, amend paragraph (a) by removing the phrase “Medicare+Choice” and adding in its place the phrase “Medicare Advantage”.

§405.450 [Amended]

10. In §405.450, amend paragraph (a) by removing the reference “§405.803” and adding in its place the reference “§498.3(b) of this chapter” and amend paragraph (b) by removing the reference “§405.803” and adding in its place “§405.924”.

§405.455 [Amended]

11. In §405.455, remove the phrase “Medicare+Choice” and add in its place the phrase “Medicare Advantage” wherever it appears.

12. Section 405.924 is amended by adding paragraph (b)(15) to read as follows:

§405.924 Actions that are initial determinations.

* * * * *

(b) * * *

(15) A claim not payable to a beneficiary for the services of a physician who has opted-out.

* * * * *

13. Section 405.2413 is amended by—

A. Amending paragraph (a)(4) by removing “;” and by adding in its place “; and”.

B. Revising paragraph (a)(5).

C. Removing paragraph (a)(6).

The revision reads as follow:

§405.2413 Services and supplies incident to a physician's services.

(a) * * *

(5) Furnished under the direct supervision of a physician.

* * * * *

14. Section 405.2415 is amended by—

A. Revising the section heading and paragraph (a)(5).

B. Removing paragraph (a)(6).

The revision reads as follows:

§405.2415 Services and supplies incident to nurse practitioner, physician assistant, or certified nurse-midwife services.

(a) * * *

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse- midwife.

* * * * *

15. Section 405.2452 is amended by—

A. Amending paragraph (a)(4) by removing ";" and by adding in its place "; and".

B. Revising paragraph (a)(5).

C. Removing paragraph (a)(6).

The revision reads as follows:

§405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) * * *

(5) Furnished under the direct supervision of a clinical psychologist or clinical social worker.

* * * * *

16. Section 405.2463 is revised to read as follows:

§405.2463 What constitutes a visit.

(a) Visit--General. (1) For RHCs, a visit is either of the following:

(i) Face-to-face encounter between a RHC patient and one of the following:

(A) Physician.

(B) Physician assistant.

(C) Nurse practitioner.

(D) Certified nurse midwife.

(E) Visiting registered professional or licensed practical nurse.

(G) Clinical psychologist.

(H) Clinical social worker.

(ii) Qualified transitional care management service.

(2) For FQHCs, a visit is either of the following:

(i) A visit as described in paragraph (a)(1)(i) or (ii) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

(b) Visit--Medical. (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

(i) Physician.

(ii) Physician assistant.

(iii) Nurse practitioner.

(iv) Certified nurse midwife.

(v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

(i) Medical nutrition therapy visit.

(ii) Diabetes outpatient self-management training visit.

(3) Visit--Mental health. A mental health visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

(i) Clinical psychologist.

(ii) Clinical social worker.

(iii) Other RHC or FQHC practitioner, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) Visit--Multiple. (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;

(ii) Has a medical visit and a mental health visit on the same day; or

(iii) Has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, Medicare pays RHCs and FQHCs for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under the prospective payment system, Medicare pays for more than 1 visit per day when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or

(ii) Has a medical visit and a mental health visit on the same day.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

17. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

18. Section 410.26 is amended by revising paragraphs (b)(5) and (b)(6) to read as follows:

§410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(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) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

* * * * *

19. Section 410.37 is amended by revising paragraph (a)(1)(iii) to read as follows:

§410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

(a) * * *

(1) * * *

(iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.

* * * * *

20. Section 410.59 is amended by revising paragraph (c)(1)(ii) to read as follows:

§410.59 Outpatient occupational therapy services: Conditions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

21. Section 410.60 is amended by revising paragraph (c)(1)(ii) to read as follows:

§410.60 Outpatient physical therapy services: Conditions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

22. Section 410.62 is amended by revising paragraph (c)(1)(ii) to read as follows:

§410.62 Outpatient speech-language pathology services: Conditions and exclusions.

* * * * *

(c) * * *

(1) * * *

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

* * * * *

23. Section 410.78 is amended by revising paragraph (b) introductory text and paragraph (f) to read as follows:

§410.78 Telehealth services.

* * * * *

(b) General rule. Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

(f) Process for adding or deleting services. Changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. A list of the services covered as telehealth services under this section is available on the CMS website.

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 411.15 is amended by adding paragraph (p)(2)(xvii) to read as follows:

§411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(xvii) Those RHC and FQHC services that are described in §405.2411(b)(2) of this chapter.

* * * * *

PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

26. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 1206 of Pub. L. 113-67, and sec. 112 of Pub. L. 113-93.

§412.64 [Amended]

27. In 412.64—

A. Amend paragraph (d)(4)(ii)(A) by removing the phrase "to April 1 of the year before the payment adjustment year" and adding in its place the phrase "to April 1 of the year before the payment adjustment year, or a later date specified by CMS".

B. Amend paragraph (d)(4)(ii)(A) by removing the phrase "by April 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "by April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

C. Amend paragraph (d)(4)(ii)(B)(1) by removing the phrase "April 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

D. Amend paragraph (d)(4)(ii)(B)(2) by removing the phrase "April 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "April 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITY SERVICES

28. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 3201 of Pub. L. 112-96 (126 Stat. 156), and sec. 632 of Pub. L. 112-240 (126 Stat. 2354).

§ 413.70 [Amended]

29. Amend §413.70 by:

A. Amending paragraph (a)(6)(ii) introductory text by removing the phrase "no later than November 30 after the close of the applicable EHR reporting period" and adding in its place the phrase " no later than November 30 after the close of the applicable EHR reporting period, or a later date specified by CMS ".

B. Amending paragraph (a)(6)(ii)(A) by removing the phrase "to November 30 after the end of the payment adjustment year" and adding in its place the phrase "to November 30 after the end of the payment adjustment year, or a later date specified by CMS".

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

30. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

31. Section 414.24 is amended by—

A. Revising the section heading, and paragraphs (a) and (b).

B. Redesignating paragraph (c) as paragraph (d).

C. Adding new paragraph (c).

The revisions and addition read as follows:

§414.24 Publication of RVUs and direct PE inputs.

(a) Definitions. For purposes of this section, the following definitions apply:

Existing code means a code that is not a new code under paragraph (c)(2) of this section, and includes codes for which the descriptor is revised and codes that are combinations or subdivisions of previously existing codes.

New code means a code that describes a service that was not previously described or valued under the PFS using any other code or combination of codes.

(b) Revisions of RVUs and Direct PE Inputs. For valuations for calendar year 2017 and beyond, CMS publishes, through notice and comment rulemaking in the **Federal Register** (including proposals in a proposed rule), changes in RVUs or direct PE inputs for existing codes.

(c) Establishing RVUs and Direct PE inputs for new codes.

(1) General rule. CMS establishes RVUs and direct PE inputs for new codes in the manner described in paragraph (b) of this section.

(2) Exception for new codes for which CMS does not have sufficient information. When CMS determines for a new code that it does not have sufficient information to include proposed RVUs or direct PE inputs in the proposed rule, but that it is in the public interest for Medicare to use a new code during a payment year, CMS will publish in the **Federal Register** RVUs and direct PE inputs that are applicable on an interim basis subject to public comment. After considering public comments and other information on interim RVUs and PE inputs for the new code, CMS publishes in the **Federal Register** the final RVUs and PE inputs for the code.

* * * * *

32. Section 414.90 is amended by—

A. In paragraph (b) by revising the definition of "Measures group".

B. In paragraphs (h)(5)(i)(B), (h)(5)(v), (j)(5)(i)(B) and (j)(5)(v) remove the phrase "CG CAHPS" and add in its place the phrase "CAHPS for PQRS".

C. In paragraphs (h)(4)(v) and (j)(4)(vi) remove the phrase "CAHPS" and add in its place the phrase "CAHPS for PQRS".

D. Redesignate paragraphs (j)(4) and (j)(5) as (j)(5) and (j)(6), respectively.

E. Adding new paragraphs (j)(4), (j)(7), (k)(4) and (m)(3).

F. Revising paragraph (m)(1).

The revisions read as follows:

§414.90 Physician Quality Reporting System (PQRS).

* * * * *

(b) * * *

Measures group means 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.

* * * * *

(j) * * *

(4) Satisfactory Reporting Criteria for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2017 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 2017 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 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures 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]

(ii) Via Qualified Registry. (A) For the 12-month 2017 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 9 measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional must report on at least 1 measure contained in the cross-cutting measure set specified by CMS. If less than 9 measures apply to the eligible professional, report up to 8 measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(ii) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(2) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) Via EHR Direct Product. For the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report 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 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's 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 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.

* * * * *

(7) Satisfactory reporting criteria for group practices for the 2017 PQRS payment adjustment. A group practice who wishes to meet the criteria for satisfactory reporting for the 2017 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 2017 PQRS payment adjustment reporting period, for a group practice of 25 to 99 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 report on 100 percent of 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 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains 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; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practice must report up to 8 measures 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. Of the measures reported, 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 contained in the

cross-cutting measure set specified by CMS. Measures with a 0 percent performance rate would not be counted; or

(iii) Via EHR Direct Product. For a group practice of 2 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's direct EHR product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report 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 to 99 eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If a group practice's 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 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, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report at least 6 additional measures covering at least 2 of the NQS domains using a qualified registry. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. 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 specified by CMS.

(vi) Via a Certified Survey Vendor in addition a Direct EHR Product or EHR Data Submission Vendor. For a group practice of 2 or more eligible professionals, for the 12-month 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures 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 that is CEHRT or EHR data submission vendor product that is CEHRT. If less than 6 measures apply to the group practice, the group practice must report up to 5 measures. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, the group practice must 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 2017 PQRS payment adjustment reporting period, report all CAHPS for PQRS survey measures via a CMS-certified survey vendor and report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(B) [Reserved]

(k) * * *

(4) Satisfactory participation criteria for individual eligible professionals for the 2017 PQRS payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a QCDR for the 2017 PQRS payment adjustment must report information on quality measures identified by the QCDR in one of the following manner:

(i) For the 12-month 2017 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 2 outcome measures, or, if 2 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, efficiency/appropriate use or patient safety.

(ii) [Reserved]

* * * * *

(m) * * *

(1) To request an informal review for reporting periods that occur prior to 2014, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. To request an informal review for reporting periods that occur in 2014 and subsequent years, an eligible professional or group practice must submit a request to CMS within 60 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

* * * * *

(3) If, during the informal review process, CMS finds errors in data that was submitted by a third-party vendor on behalf of an eligible professional or group practice using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors.

(i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO web interface reporting mechanisms.

(ii) CMS will only allow resubmission of data that was already previously submitted to CMS.

(iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

* * * * *

§414.511 [Removed]

33. Section §414.511 is removed.

34. Section 414.610 is amended by revising paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) to read as follows:

§414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through March 31, 2015, ambulance services originating in:

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through March 31, 2015, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

35. Section 414.1200 is amended by revising paragraphs (a) and (b)(5) to read as follows:

§414.1200 Basis and scope.

(a) Basis. This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians and starting in 2017 to a group and a solo practitioner under the Medicare Physician Fee Schedule based on the quality of care furnished compared to cost during a performance period.

(b) * * *

(5) Additional measures for groups and solo practitioners.

* * * * *

36. Section 414.1205 is amended by—

A. Revising the definitions of "Group of physicians" and "Value-based payment modifier."

B. Adding the definition of "Solo practitioner" in alphabetical order.

The addition and revisions read as follows:

§414.1205 Definitions.

* * * * *

Group of physicians (Group) means a single Taxpayer Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

* * * * *

Solo practitioner means a single Taxpayer Identification Number (TIN) with one eligible professional who is identified by an individual National Provider Identifier (NPI) billing under the TIN.

* * * * *

Value-based payment modifier means the percentage as determined under §414.1270 by which amounts paid to a group or solo practitioner under the Medicare Physician Fee Schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

37. Section 414.1210 is amended by—

A. Adding paragraphs (a)(3), (a)(4), (b)(2), (b)(3), and (b)(4).

B. Revising paragraph (c).

The additions and revision reads as follows:

§414.1210 Application of the value-based payment modifier.

(a) * * *

(3) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners based on the performance period for the payment adjustment period as described at §414.1215.

(4) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners based on the performance period for the payment adjustment period as described at §414.1215.

(b) * * *

(2) Application of the value-based payment modifier to participants in the Shared Savings Program.

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at §414.1215. The value-based payment modifier for a group or solo practitioner that participates in an ACO under the Shared Savings Program during the performance period is determined based on paragraphs (b)(2)(i)(A) through (D) of this section.

(A) The cost composite is classified as "average" under §414.1275(b).

(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) or another mechanism specified by CMS and the ACO all-cause readmission measure.

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to – 4% for groups with 10 or more eligible professionals and equal to – 2% for groups with two to nine eligible professionals and for solo practitioners.

(D) 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.

(ii) For the CY 2018 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to nonphysician eligible professionals in groups with 2 or more eligible professionals and to nonphysician eligible professionals who are solo practitioners that participate in an ACO under the Shared Savings Program during the performance period for the payment adjustment period as described at §414.1215. The value-based payment modifier for nonphysician eligible professionals is determined in the same manner as for physicians as described under paragraphs (b)(2)(i)(A) through (D) of this section.

(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 applicable to physicians in groups with 2 or more eligible professionals and to 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. 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 is participating in the Pioneer ACO Model or CPC Initiative in the performance period. The value-based payment modifier for groups and solo practitioners that participate in the Pioneer ACO Model or the CPC Initiative during the performance period is determined based on paragraphs (b)(3)(i)(A) through (C) of this section.

(A) The cost composite is classified as “average” under §414.1275(b).

(B) The quality composite is classified as “average” under §414.1275(b).

(C) 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 Pioneer ACO or CPC site during the performance period.

(4) Application of the value-based payment modifier to participants in other similar Innovation Center models or CMS initiatives.

(i) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier is applicable to physicians in groups with 2 or more eligible professionals and to physicians who are solo practitioners that participate in other similar Innovation Center models or CMS initiatives during the performance period for the payment adjustment period as described at §414.1215. For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model or CMS initiative if at least one eligible professional billing under the TIN in the performance period is participating in the model or initiative in the performance period. The value-based payment modifier for groups and solo practitioners that participate in a similar Innovation Center model or CMS initiative is determined based on paragraphs (b)(3)(i)(A) through (C) of this section.

(ii) [Reserved]

(c) Group size determination. The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at §414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis,

the group did not have the required number of eligible professionals, as defined in §414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

§414.1220 [Amended]

38. In §414.1220, remove the phrase "Groups of physicians" and add in its place the phrase "Solo practitioners and groups".

39. Section 414.1225 is revised to read as follows:

§414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which solo practitioners and groups (or individual eligible professionals within such groups) are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in §414.1215, to the extent a solo practitioner or a group (or individual eligible professionals within such group) submit data on such measures.

40. Section 414.1230 is amended by revising the section heading and the introductory text to read as follows:

§414.1230 Additional measures for groups and solo practitioners.

The value-based payment modifier includes the following additional quality measures (outcome measures) as applicable for all groups and solo practitioners subject to the value-based payment modifier:

* * * * *

§414.1235 [Amended]

41. In §414.1235, amend paragraph (a) introductory text, by removing the phrase "of physicians subject" and add in its place the phrase "and solo practitioners subject".

42. Section 414.1240 is revised to read as follows:

§414.1240 Attribution for quality of care and cost measures.

(a) Beneficiaries are attributed to groups and solo practitioners subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under §425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.

(b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group or the solo practitioner subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's or solo practitioner's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at §414.1215.

§414.1245 [Amended]

43. In §414.1245, amend the introductory text, by removing the phrase "of physicians subject" and add in its place the phrase "and solo practitioner subject".

44. Section 414.1250 is revised 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, EHR, 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.

(b) The benchmark for each outcome measure under §414.1230, is the national mean for that 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 paragraphs (b) and (c) to read as follows:

§414.1255 Benchmarks for cost measures.

* * * * *

(b) 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. Each national specialty-specific expected cost is weighted by the proportion of each specialty in the group, the number of eligible professionals of each specialty in the group, and the number of beneficiaries attributed to the group.

(c) The national specialty-specific expected costs referenced in paragraph (b) of this section are derived by calculating, for each specialty, the average cost of beneficiaries attributed to groups and solo practitioners that include that specialty.

46. Section 414.1265 is amended by revising the introductory text and paragraph (a) to read as follows:

§414.1265 Reliability of measures.

To calculate a composite score for a quality measure or a cost measure, a group or solo practitioner subject to the value-based payment modifier must have 20 or more cases for that measure.

(a) In a performance period, if a group or solo practitioner has fewer than 20 cases for a measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(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 or a solo practitioner 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) [Reserved]

* * * * *

47. Section 414.1270 is amended by revising paragraph (b)(4) and adding paragraph (c) to read as follows:

§414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(b) * * *

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 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).

* * * * *

(c) For the CY 2017 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 and a downward payment adjustment of -4.0 percent will be applied to a group with 10 or more 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 self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 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 2017 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 2017 as specified by CMS.

(2) For a group comprised of 10 or more eligible professionals that is not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(i).

(3) For a group comprised of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (c)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(3)(ii).

(4) If at least fifty percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2017 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).

(5) 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 with at least 20 cases.

48. Section 414.1275 is amended by—

A. Revising paragraph (a).

B. Redesignating paragraphs (d) introductory text, (d)(1), and (d)(2) as paragraphs (d)(1) introductory text, (d)(1)(i), and (d)(1)(ii), respectively.

C. Adding paragraphs (c)(3) and (d)(2).

The revision and additions read as follows:

§414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group and a solo practitioner subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

* * * * *

(c) * * *

(3) The following value-based payment modifier percentages apply to the CY 2017 payment adjustment period:

(i) For groups with 10 or more eligible professionals:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0%	+2.0x*	+4.0x*
Average Cost	-2.0%	+0.0%	+2.0x*
High Cost	-4.0%	-2.0%	+0.0%

*Groups eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(ii) For groups with two to nine eligible professionals and solo practitioners:

CY 2017 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND SOLO PRACTITIONERS

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	+0.0%	+0.0%	+1.0x*
High Cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting 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) * * *

(2) 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 2017 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 or +3x (rather than +2x) if a solo practitioner or the group has two to nine 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 or +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals.

§414.1285 [Amended]

49. In §414.1285, remove the phrase "of physicians may" and add in its place the phrase "and a solo practitioner may".

PART 425--MEDICARE SHARED SAVINGS PROGRAM

50. 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).

51. Section 425.308 is amended by revising paragraph (e) to read as follows:

§425.308 Public reporting and transparency.

* * * * *

(e) Results of claims based measures. All quality measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

52. Section 425.502 is amended by--:

A. In paragraph (a)(1), removing the phrase "of an ACO's agreement, CMS" and adding in its place the phrase "of an ACO's first agreement period, CMS"

B. In paragraph (b)(2)(ii), removing the phrase "80.00 percent." and adding in its place the phrase "80.00 percent, or when the 90th percentile is equal to or greater than 95 percent."

C. Revising paragraph (a)(2).

D. Adding paragraphs (a)(3), (a)(4), (b)(4), and (e)(4).

The revision and additions read as follows:

§425.502 Calculating the ACO quality performance score.

(a) * * *

(2) During subsequent performance years of the ACO's first agreement period, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures.

(3) Under the quality performance standard for each performance year of an ACO's subsequent agreement period, the ACO must continue to report on all measures but the ACO will be assessed on performance based on the quality performance benchmark and minimum attainment level of certain measures.

(4) The quality performance standard for a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods for which reporting of the measure is required. For subsequent reporting periods, the quality performance standard for the measure will be assessed according to the phase-in schedule for the measure.

(b) * * *

(4)(i) CMS will update the quality performance benchmarks every 2 years.

(ii) For newly introduced measures that transition to pay for performance in the second year of the 2-year benchmarking cycle, the benchmark will be established for that year and updated along with the other measures at the start of the next 2-year benchmarking cycle.

(iii) CMS will use up to three years of data, as available, to set the benchmark for each quality measure.

* * * * *

(e) * * *

(4)(i) ACOs that demonstrate quality improvement on established quality measures from year to year will be eligible for up to 4 bonus points per domain.

(ii) Bonus points are awarded based on an ACO's net improvement in measures within a domain, which is calculated by determining the total number of significantly improved measures and subtracting the total number of significantly declined measures.

(iii) Up to four bonus points are awarded based on a comparison of the ACO's net improvement in performance on the measures for the domain to the total number of individual measures in the domain.

(iv) When bonus points are added to points earned for the quality measures in the domain, the total points received for the domain may not exceed the maximum total points for the domain in the absence of the quality improvement measure.

(v) If an ACO renews its participation agreement for a subsequent agreement period, quality improvement will be measured based on a comparison between performance in the first year of the new agreement period and performance in the third year of the previous agreement period.

53. Section 425.506 is amended by revising the section heading and adding paragraph (d) to read as follows:

§425.506 Incorporating reporting requirements related to adoption of Electronic health records technology.

* * * * * *

(d) Eligible professionals participating in an ACO under the Shared Savings Program satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program when the following occurs:

(1) The eligible professional extracts data necessary for the ACO to satisfy the quality reporting requirements under this subpart from certified EHR technology.

(2) The ACO reports the ACO GPRO measures through a CMS web interface.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

54. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

55. Section 489.20 is amended by adding paragraph (s)(17) to read as follows:

§489.20 Basic commitments.

* * * * *

(s) * * *

(17) Those RHC and FQHC services that are described in § 405.2411(b)(2) of this

chapter.

* * * * *

PART 495--STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

56. 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).

§495.102 [Amended]

57. In 495.102—

A. Amend paragraph (d)(4)(i) by removing the phrase in the first sentence "to July 1 of the year preceding the payment adjustment year" and adding in its place the phrase "to July 1 of the year preceding the payment adjustment year, or a later date specified by CMS".

B. Amend paragraph (d)(4)(i) by removing the phrase in the second sentence "no later than July 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

C. Amend paragraph (d)(4)(iii)(A) by removing the phrase in the second sentence "no later than July 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

D. Amend paragraph (d)(4)(iii)(B) by removing the phrase in the second sentence "by July 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

E. Amend the introductory text of paragraph (d)(4)(iv) introductory text by removing the phrase "by July 1 of the year before the applicable payment adjustment year" and adding in its place the phrase "by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS".

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

58. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

59. Section 498.3 is amended by adding paragraph (b)(19) to read as follow:

§498.3 Scope and applicability.

* * * * *

(b) * * *

(19) Whether 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, or failed to properly terminate opt-out.

* * * * *

Dated: October 22, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 28, 2014.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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